

WIDEX **ZEN**^{2GO}[™]

USER INSTRUCTIONS **WIDEX ZEN2GO**[™]

C2-PA (RIC)
tinnitus devices



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SYMBOLS

The following symbols will be used throughout the manual:



WARNING

Messages with this heading indicate serious adverse reactions, potential safety hazards and inadequate performance of device.




CAUTION

Messages with this heading indicate/include information regarding any special care to be exercised.



Non-ionizing radiation.



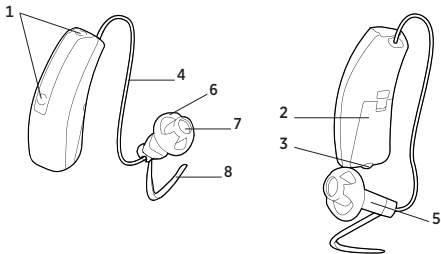
 Not for general waste.

DESCRIPTION

Your WIDEX ZEN2GO package includes two C2-PA tinnitus devices and an RC-DEX remote control. The devices are provided with ear-sets, which consist of an earwire and an open ear-tip in which the receiver is placed. The devices use a proprietary wireless technology, WidexLink, to enable communication between them. The devices provide Zen listening programs, which make musical tones and/or a rushing noise in the background.

The illustrations below show the tinnitus devices.

1. Microphone openings
2. Battery drawer (on/off function)
3. Nail grip
4. Earwire
5. Receiver
6. Ear-tip
7. Wax guard
8. Anchor





WARNING

This booklet contains important information and instructions. Please read this booklet carefully before you start using the tinnitus devices.

NOTE

The descriptions provided in this manual apply to both tinnitus devices.

Please also read “User instructions - RC-DEX remote control for Widex tinnitus devices”.

Indications for use

The Zen program is intended to provide a relaxing sound background for adults (21 years and older) who desire to listen to such a background in quiet. It may be used as a sound therapy tool in a tinnitus treatment program that is programmed by a licensed hearing care professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

Acoustic indicators

The tinnitus devices may be set to produce a signal to indicate the use of certain functions.

Functions	Settings
Adjusting volume via remote control	Tone
Confirming RC program key use	Clicking sound
Changing program via remote control	Clicking sound
Starting up the device	Tone
Warning about low battery	4 tones

The battery

We recommend **zinc-air batteries**. Use a **size 10** battery for the devices.

To obtain replacement batteries, please consult your hearing care professional. It is important to take note of the expiration date and the recommendations regarding disposal of used batteries on the battery pack.



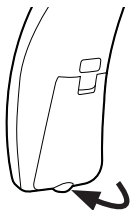
Inserting the battery

Before inserting a new battery into the device, remember to remove the adhesive tab. Once the tab has been removed, the battery will start functioning after a few seconds.



CAUTION

Do not use batteries if there is a sticky residue from the tab or other unwanted substance, as this can cause the device to malfunction.



Use the nail grip to gently swing the battery drawer open. Do not press the drawer beyond the open position.

Place the battery in the drawer as illustrated, so that the plus (+) sign on the battery is facing towards you when you hold the device as shown. You can use the battery magnet provided to steer the battery into place.



If the battery drawer does not close easily, the battery is incorrectly inserted.

When changing battery, it is a good idea to hold the device over a table.

Low battery indication

An acoustic indicator will sound when the battery is nearly exhausted, unless this function has been disabled. Exactly how long the device will function after the low battery indication varies from one case to another. We recommend that you always have a spare battery with you.

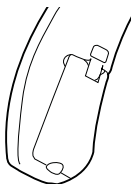


WARNING

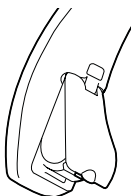
Never leave an exhausted battery in the device. Exhausted batteries may leak, damaging the device.

Turning the device on and off

The battery drawer of the device also functions as the on/off switch.



Close the battery drawer to turn on the device. An acoustic indicator will indicate that the device has been switched on unless this function has been disabled.



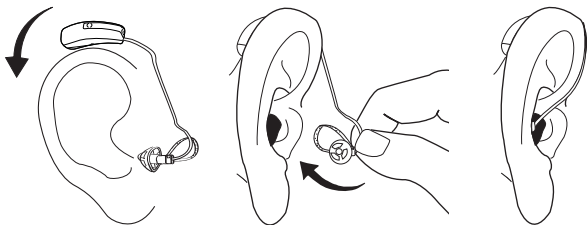
Open the battery drawer to turn off the device.

Please remember to turn off the device when it is not in use. Remove the battery if the device will not be used for several days.

Positioning the device

Insert the ear-tip in the ear canal while holding the lower part of the earwire. It may help to pull the outer ear backwards and upwards with the opposite hand.

Place the device behind the ear, so that the device and earwire rest comfortably on the ear, close to your head.

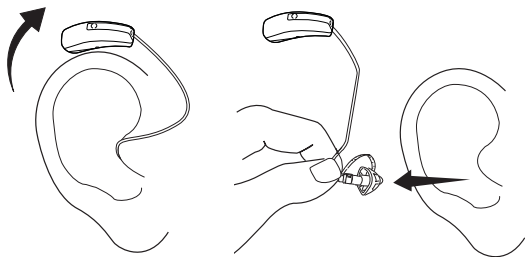


An anchor is used with the open ear-tip to help secure the device in the ear. Please refer to the section: The anchor.

Removing the device

Remove the device from its position behind the ear.

Carefully pull the ear-tip out of the ear canal, while holding the lower part of the earwire.



Volume adjustment

The remote control allows you to fine-tune the volume. Any volume adjustment via the remote control will affect both devices.

Please also refer to the user instructions for the remote control.



CAUTION

If the volume in the device is generally too loud or too weak, or the reproduced sounds are distorted, or if you would like any further information, consult your hearing care professional.

To mute the device with the remote control:

Keep pressing the volume down key on the remote control after the long beep-tone has sounded and until it stops. Pressing one of the volume keys briefly will bring back the sound.

Listening programs

Your devices have a start-up program and three sound stimulation programs called Zen programs.

Start-up	The devices are prefitted to 10 dB HTL and no Zen tones or Zen noise.
Zen A	Tones
Zen B	Tones and Noise
Zen C	Noise

Switching between the programs

When you turn on your tinnitus devices, they will be in the start-up program. From this program you access the Zen program mode by a long press (more than 1 second) on the program key of the remote control. A short press then allows you to cycle through the available Zen programs. You can return to the start-up program by pressing and holding the program key for more than a second.

The Zen programs

Because of the unique ways in which Zen is programmed in your device, please follow the recommendations of your hearing care professionals as to how to use the programs, when to use the programs and/or how long.

**CAUTION**

Use of the different Zen programs may interfere with hearing surrounding sounds including speech. Zen should not be used when hearing such sounds is important.

**CAUTION**

If after two days of use you perceive a decrease in loudness, tolerance of sounds, speech not as clear, or worsening tinnitus, contact your hearing care professional.

Benefits

The Zen program may provide a relaxing listening background for some people. When the Zen program is used in a tinnitus management program, its wearer may experience some relief from tinnitus.

Precautions

To ensure the safety and effectiveness of the Zen programs when used as a sound therapy tool for tinnitus, the tinnitus management program must be designed and conducted by hearing care professionals who are trained in tinnitus management. A tinnitus management program should include a complete audiological evaluation, tinnitus diagnosis, counseling, use of proper amplification and/or sound therapy tools.

Prior to any tinnitus management program, it is advisable that you seek medical attention to exhaust any medical or surgical treatment options.

Use your devices and the Zen programs according to the directions and schedule recommended by your hearing care professionals.

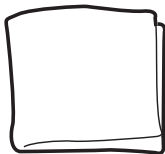
Risks

There are no known risks or side effects associated with the use of the Zen program. However, consistent with our recommendations on the use of conventional hearing aids, stop using the tinnitus devices (and the Zen program) and seek attention from your hearing care professional if any of the following symptoms are noted:

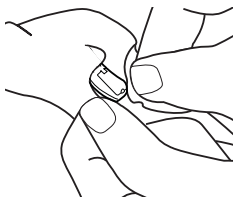
- Skin irritation
- Perceived decrease in loudness, tolerance of sounds, speech not as clear, or worsening tinnitus

Cleaning

For cleaning your device and ear-set a cloth is provided.



Contact your hearing care professional if you need a new cloth.



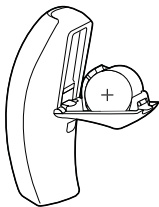
Cleaning the device

Clean the device after use with the cloth provided.



WARNING

Never use water or cleaning solutions to clean the device, as this may cause it to malfunction.



When the device is not in use, keep it in a warm, dry place with the battery drawer open to ventilate the device and allow it to dry.

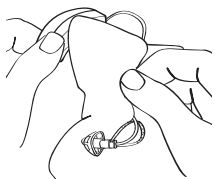
Cleaning the ear-set

Make sure that your **ear-set** is always clean and free of earwax, moisture and the like.



WARNING

Never use alcohol or other cleaning solutions to clean the ear-set, as this can discolour it.



Clean the **earwire** with the cloth after use.



WARNING

Never use water or cleaning solutions to clean the earwire. The receiver must **never** come into contact with water, as this can damage the receiver.

If dirt has collected on the receiver, use the cloth to remove it, after first pulling the receiver out of the ear-tip.



If necessary, the open ear-tip can be rinsed thoroughly in lukewarm water, **after disconnecting it from the rest of the ear-set.** Allow it to dry overnight.

Placing the ear-tip on the earwire

Gently insert the receiver at the end of the earwire into the ear-tip until it touches the end. It is very important to ensure that the ear-tip is firmly secured.

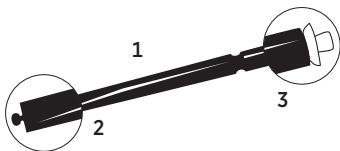


THE NANOCARE WAX GUARD

The NanoCare wax guard helps to protect the device against earwax. Always use NanoCare wax guards with your device. Otherwise the warranty for the device will be void.

The wax guard system consists of the following parts:

1. Holder
2. Removal hook
3. Wax guard

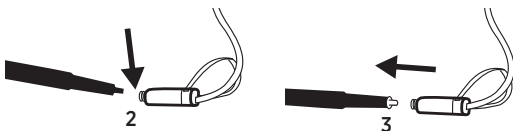


CAUTION

The wax guard is disposable and for one-time use only. Do not attempt to clean or reuse a wax guard. This could damage your device and/or cause the wax guard to become dislodged in your ear.

Changing the wax guard

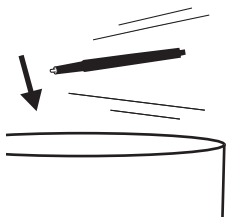
1. Remove the ear-tip from the earwire
2. Insert the removal hook into the used wax guard placed in the sound outlet.
3. Pull the wax guard straight out.



Now turn the holder around so that the used wax guard is away from the receiver and the new one is in position to be inserted.

4. Insert the holder into the opening of the sound outlet and gently press the wax guard onto the receiver.
5. Pull the holder straight out. The new wax guard will automatically detach from the holder. Press the receiver gently against a flat surface to ensure that the wax guard remains in place.
6. Place the ear-tip on the earwire.





Discard the holder with the used wax guard.

The frequency with which the wax guard should be changed varies from one individual to another.

If you have any questions regarding your wax guard, please contact your hearing care professional.



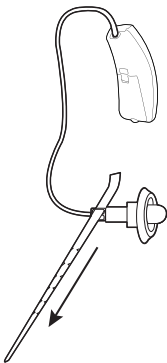
WARNING

If the wax guard fits loosely, discard it and insert another. If the wax guard becomes dislodged while the ear-tip is placed in the ear canal, please contact your physician. Do not try to remove the wax guard from your ear canal yourself.

THE ANCHOR



The anchor is supplied separately from the rest of the ear-set and can be used in different ways. Firstly, we show how the anchor can be used without prior trimming:



Pull the pointed end of the anchor through the upper hole on the receiver located at the end of the earwire.

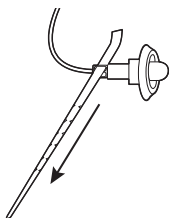
The angled grip should be pointing towards the device.

Continue pulling until the anchor is stopped by the grip at the end.



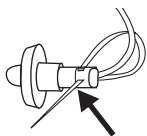
Your ear-set is now ready for use and is positioned so that it rests comfortably in your ear.

The anchor can also be trimmed to fit your ear:



Pull the pointed end of the anchor through the upper hole on the receiver located at the end of the earwire. The angled grip should be pointing towards the device.

Continue pulling until the anchor is stopped by the grip at the end. Now turn the ear-set around.



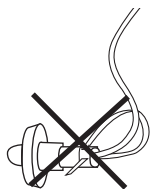
Then guide the pointed end of the anchor through the lower hole to form a loop.



When the loop is the correct size, cut any excess off, leaving only the loop.

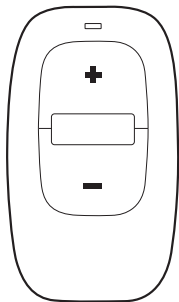


The anchor loop has the correct size when it supports the position of the ear-tip in the ear canal, and the ear-set sits securely in and on the ear.



Take great care to cut off all the excess so that the end of the anchor loop is flush with the small hole and there are no sharp edges. Use the tip of your finger to check for sharp edges. If part of the anchor sticks out through the hole, creating an uneven surface, this may cause irritation of the ear.

RC-DEX REMOTE CONTROL



A remote control is supplied with your devices. Please refer to the “RC-DEX for Widex tinnitus devices” user instructions for further information.

IN CASE OF MALFUNCTION

Problem	Potential cause	Solution
The device is dead	The device is not turned on	Make sure the battery drawer is closed
	The earwire is broken	Contact your hearing care professional
	The battery does not work	Insert a new battery in the battery drawer of the device
	The NanoCare wax guard is blocked	Change the wax guard
The device volume is not powerful enough	The NanoCare wax guard is blocked	Change the wax guard
	Your ear is blocked by earwax	Contact your ENT doctor/physician
	Your hearing/tinnitus may have changed	Contact your hearing care professional
The device whistles continuously	Your ear is blocked by earwax	Contact your ENT doctor/physician
	The ear-tip is not correctly placed in your ear canal	Take the ear-tip out and reinsert it
	The ear-tip fit is too loose	Contact your hearing care professional
	The receiver is not adequately secured in the ear-tip	Replace the ear-tip. If the problem persists, contact your hearing care professional

Problem	Potential cause	Solution
Your two devices are not working in synchrony	The connection between the devices is lost	Turn the devices off and on again
The devices do not respond with a corresponding change in volume or program to the RC-DEX	<ul style="list-style-type: none"> a. The RC-DEX is used beyond the transmission range (> 1 m /approx. 3ft) b. Strong electromagnetic interference in the vicinity c. The RC-DEX and the devices are not matched 	<ul style="list-style-type: none"> a. Move the RC-DEX closer to the devices b. Move away from known source of EM interference c. Check with dispenser to make sure RC-DEX is matched with devices

CARING FOR YOUR TINNITUS DEVICES

Your tinnitus device is a valuable object and should be treated with care. Here are some things you can do to prolong the life of your device:



CAUTION

- Turn off your device when it is not in use. Remove the battery if the device will not be used for several days.
- When the device is not in use, keep it in its case in a dry location out of reach of children and pets.
- Do not expose the device to extreme temperatures or high humidity. Make sure to dry the device thoroughly after heavy perspiration such as that which may occur during intense physical activity, e.g. playing sports.
- Avoid dropping your device – perform cleaning and battery changes while holding the device above a soft surface.
- Do not wear your device while in the shower or swimming, or when using a hair dryer, perfume, hair and body sprays or gels such as suntanning lotions or creams.

WARNINGS



WARNING

Tinnitus devices and batteries can be dangerous if swallowed or used improperly. Swallowing or improper use can result in severe injury or even fatalities. In case of ingestion, contact a physician immediately and the 24 Hour National Button Battery Ingestion Hotline at (202) 625-3333.

- Keep tinnitus devices and their parts, accessories and batteries out of reach of children and anyone else who might swallow such items or otherwise cause injury to themselves. Do not change batteries in front of them and do not let them see where you keep your battery supply. Discard used batteries carefully.
- Batteries are very small and can easily be mistaken for pills or the like. Never put a battery or device in your mouth for any reason as you may risk swallowing it.
- Risk of explosion if battery is replaced by an incorrect type or recharged. Dispose of used batteries according to the instructions.
- Never allow others to wear your device.
- The device is made of modern non-allergenic materials. Nonetheless, in rare cases skin irritation may occur. If you notice skin irritation in or around your ear or ear canal, contact your hearing care professional.



WARNING

- Be aware that the use of tinnitus devices may involve a slightly increased risk of infection in the ear canal. An infection can arise as a result of inadequate ventilation of the ear. We therefore recommend that you remove the device and ear-set from your ear at night to allow the ear canal to be ventilated. Make sure that you clean and inspect your device and ear-set as required. If an infection occurs, you should seek medical attention and contact your hearing care professional for advice on how to disinfect the various device parts. Do not under any circumstances use alcohol, chlorine or similar substances.
- Regular use of a de-humidifier is recommended to help avoid malfunction of the device.
- Do not use Widex tinnitus devices in mines or other areas with explosive gases.
- **Do not wear your device during radiation, X-rays, MRIs, CT or other medical treatments and scans.** The emissions from these procedures as well as from other types of radiation, such as that in a microwave oven, can damage your device. Radiation from, for example, room surveillance equipment, burglar alarms and cell phones is weaker and will not damage the device but may create audible interference.



CAUTION

- Your device has been tested for interference according to international standards. Nevertheless, it is possible that unforeseen interference may occur in the device due to electromagnetic radiation from other products such as alarm systems, room surveillance equipment and cell phones.
- Although your device has been designed to comply with the most stringent international electromagnetic compatibility standards, the possibility cannot be excluded that it may cause interference with other equipment, such as medical devices.
- Never try to open or repair the device yourself.

ADVICE

NOTE

- The use of the devices increases the risk of accumulation of earwax. Contact your physician/ENT doctor if you suspect that a plug of earwax has accumulated in your ear. Earwax may not only reduce your own hearing but also the effect of the device considerably. It is a good idea to ask your physician to clean your ears a couple of times a year.

REGULATORY INFORMATION

The following Table summarizes the technical details of the WidexLink technology as it is implemented in the tinnitus devices.

	Tinnitus devices	RC-DEX	TM-DEX	Bluetooth* - NOAHlink
Antenna type	Inductive antenna	Inductive antenna	Inductive antenna	Embedded ceramic antenna
Antenna dimensions	Ø1.8 mm, L - 4.85 mm	Ø8 mm, L - 20 mm	Ø6 mm, L - 8 mm	NA
Modulation	FSK	FSK	FSK	FHSS/ GFSK, $\pi/4$ DPSK, 8 DPSK
Magnetic Field Strength (at 10 m distance)	-54 dB μ A/m	-13 dB μ A/m	-26 dB μ A/m	NA
Output power (EIRP**)	29 pW	21 nW	1.2 nW	+4dB re. 1mW
Range	< 1 m re-remote unit to tinnitus device < 30 cm between tinnitus devices or tinnitus device to TM-DEX	< 1 m re-remote unit to tinnitus device	< 30 cm between tinnitus device and TM-DEX	< 10 m between PC and NOAHlink

	Tinnitus devices	RC-DEX	TM-DEX	Bluetooth* - NOAHlink
Center frequency	10.6 MHz	10.6 MHz	10.6 MHz	2.4 GHz
Channel	Single channel radio	Single channel radio	Single channel radio	5 logical channels
Band-width	660 kHz (-15 dB)	660kHz (-15 dB)	660kHz (-15 dB)	1 MHz
Data-rate	212 kbit/second (raw channel capacity)	212 kbit/second (raw channel capacity)	212 kbit/second (raw channel capacity)	2.1 Mbps
Data flow	Simplex or semi-duplex capability	Simplex capability	Simplex or semi-duplex capability	Time division duplex (TDD)
Protocol	Random Access - no collision avoidance	Random Access - no collision avoidance	Random Access - no collision avoidance	Packet-based protocol, time divided; secure Serial Port Profile (SPP)

* Bluetooth specification v2.0 + EDR published by the Bluetooth Special Interest Group (SIG).

** EIRP = Equivalent isotropically radiated power.

Bluetooth Identifier: B01837

Reference number of QPN: NOAHlinkV1.2_412832_QPN_E1

(Benefits) The use of wireless transmission allows convenient and synchronized control of tinnitus device functions. The wireless tinnitus devices share input information between the two partner tinnitus devices. In so doing, the wearers would experience the following additional user benefits (only when wearing binaural tinnitus devices).

Synchronization of volume control settings between tinnitus devices – The volume in both tinnitus devices will change when the VC is adjusted on one ear.

Synchronization of listening programs between tinnitus devices – The same listening program is used in both tinnitus devices when one is changed by the user.

(Contraindications):

- Congenital or traumatic deformity of the ear
- Active drainage from the ear within 90 days
- History of rapid progressive hearing loss within previous 90 days
- Acute or chronic dizziness
- Sudden unilateral hearing loss in previous 90 days



CAUTION

(Risks) The use of the tinnitus devices/DEX should not interfere with other devices such as a pacemaker. However, to be extra cautious, Widex follows the guidelines recommended by the manufacturers of implantable defibrillators and pacemakers for their patients when using cell phones. Specifically, tinnitus device wearers who also use a pacemaker should

- Keep the tinnitus devices (and/or any of the DEX accessories) at a distance of at least 15 cm/6 inches away from the pacemaker and
- Do not carry the tinnitus devices (and/or any of the DEX accessories) in a shirt pocket or close to the chest.
- If any interference is observed, do not use the tinnitus devices (and/or DEX) and contact your pacemaker manufacturer and hearing healthcare professional immediately.

RADIO TRANSMITTER / CABLES / TRANSDUCERS

The tinnitus device contains a radio transmitter / receiver with the following

Radio transmitter parameters:

- Frequency (range): 10.6 MHz (10.2 – 11.0 MHz)
- Bandwidth (-15dB): 660 kHz
- Channel: Single channel radio
- Modulation: FSK
- Radiated output power: 29 pW / -75 dBm
- Magnetic field strength: -54 dB μ A/m @ 10 m
- Duty Cycle: < 5 % (averaged over 1 hour of operation)
- Simplex or semi duplex capability

The radio receiver in the tinnitus device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

No cables and transducers are used neither during normal use of the tinnitus device nor during programming of the tinnitus device.

QUALITY OF SERVICE FOR WIRELESS TECHNOLOGY IN THE WIDEXLINK SYSTEM

WidexLink wireless technology enables communication between two partners of a binaural pair of tinnitus devices and with their matched external devices. The requirements for the quality of service (QoS) vary among the various components and their intended user scenarios.

For programming, these requirements include a BER (Bit Error Rate) better than 10^{-3} , at a bitrate of 212 kbits/s, a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x) and a receive-to-transmit mode (RX to TX) time. The data are saved in the tinnitus device even when transmission is interrupted.

During daily use, the requirements on audio streaming between tinnitus devices include a BER better than 10^{-3} . The communication is simplex with a bitrate of 212 kbits/s. The additional audio decoding in this mode results in a longer latency which is less than 10 ms. For remote control commands the QoS requirements include a BER better than 10^{-2} . The lower BER requirement results from redundant transmissions. Each key press results in transmissions of 7 data packages of which only one is needed for a successful communication.

For inter-ear communication between tinnitus devices, a BER better than 10^{-3} is required. The communication is updated every 50 ms (or 20 Hz). The tinnitus devices continue to operate based on the last saved settings even when the transmission range is exceeded or when communication is interfered.

Wireless Security Measures

Security of the wireless signals is assured through device system design that includes:

- Individual MAC address for each unit which is checked during each transmission.
- A built-in pairing table which specifies valid and legitimate pairing among units
- A proprietary Widex communication protocol which checks the package numbers during each transmission.
- A Cyclic Redundancy Check (CRC) to check data validity and correct errors.

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic emissions

The tinnitus devices are intended for use in the electromagnetic environment specified below. The customer or the user of a tinnitus device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The tinnitus device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The tinnitus device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable *)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable *)	

*) *Battery powered equipment*

Electromagnetic immunity

The tinnitus devices are intended for use in the electromagnetic environment specified below. The customer or the user of a tinnitus device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/burst IEC 61000-4-4	± 2 kV for power line supplies ± 1 kV for input/output lines	Not applicable *) Not applicable *)	Not applicable *)
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable *) Not applicable *)	Not applicable *)

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable *)	Not applicable *)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment


NOTE U_T is the a.c. mains voltage prior to the application of the test level.

*) *Battery powered equipment*

Electromagnetic immunity – cont.

The tinnitus devices are intended for use in the electromagnetic environment specified below. The customer or the user of a tinnitus device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the tinnitus device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the tinnitus device is used exceeds the applicable RF compliance level above, the tinnitus device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the tinnitus device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Recommended separation distances between portable and mobile RF communication equipment and the tinnitus devices.

The tinnitus devices are intended for use in the electromagnetic environment in which RF disturbances are controlled. The customer or the user of the tinnitus device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the tinnitus devices as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

This tinnitus device may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements.

(EMI/EMC Compliance).

The tinnitus device complies with the following EMC/EMI standards:

Standard	Test type	Note
47 CFR Part 15, subpart C	RF emissions	USA Federal Communications Commission (FCC) requirements for intentional radiators.
EN 303 330-2 V1.3.1	RF emissions incl. Spurious emission	EMC and radio spectrum matters for Short Range Devices in the frequency range 9 kHz – 25 MHz
IEC 60601-1-2:2007 *adapted protocol	EMC emission Immunity, RF and ESD	Medical electrical equipment. General requirements for basic safety and essential performance. Electromagnetic compatibility.
EN 301 489-3 V1.4.1	Immunity, RF and ESD	Standard for Low Power Transmitters in the frequency range 9 kHz – 40 GHz
IEC 60118-13:2004	Immunity RF Near Field immunity test	International Product std. for hearing aids to ensure adequate immunity to radio interference from cell telephones.
ANSI C63.19-2001	Immunity RF Near Field immunity test	American National Standard Methods of measurement of Compatibility between wireless Communication Devices and Hearing Aids

** The device was tested in only one orientation that represents the longest length (or worst case scenario). This is acceptable because of the relative small size of the device compared to the wavelength of the RF used in the test.*

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID 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 aid. 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 assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid 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 aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid 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 aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids 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.

Children with hearing loss

In addition to seeing a physician for a 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 the 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.

FCC ID: TTY-C4PA

IC: 5676B-C4PA

Federal Communications Commission Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTE:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Changes or modifications to the equipment not expressly approved by Widex could void the user's authority to operate the equipment.

**Industry Canada Statement /
Déclaration d'industrie Canada**

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.

Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- (1) l'appareil ne doit pas produire de brouillage, et
- (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

CE 0459

Hereby, Widex A/S declares that this C2-PA is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

A copy of the Declaration of Conformity can be found at: <http://www.widex.com>

 **N26346**



Tinnitus devices, accessories and batteries should not be disposed of with normal household waste. Please consult your national Widex distributor for advice on how to dispose of these items.



CE 0459

Manufacturer

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