WIDEX **UNIQUE**™

USER INSTRUCTIONS
THE WIDEX UNIQUE™ FAMILY

U-PA model
Receiver-in-canal

WIDEX®
HIGH DEFINITION HEARING

YOUR WIDEX® HEARING AID

(To be filled out by the hearing care professional)

Your hearing aid series:

PROGRAM	
☐ Universal	☐ Audibility Extender
☐ Quiet	☐ Audibility Extender
☐ Transport	☐ Audibility Extender
☐ Urban	☐ Audibility Extender
☐ Party	☐ Audibility Extender
☐ Music	☐ Audibility Extender
SPECIAL PROGRAMS	
☐ Zen	☐ Audibility Extender
☐ Phone	☐ Audibility Extender
SMARTTOGGLE PROGRAMS	

PROGRAM	
☐ Zen+	☐ Audibility Extender

NOTE

Read this booklet and the booklet "Ear-sets for Widex hearing aids" carefully before your start using your hearing aid.

CONTENTS

YOUR WIDEX HEARING AID

Welcome to Widex

Congratulations on your new hearing aid.

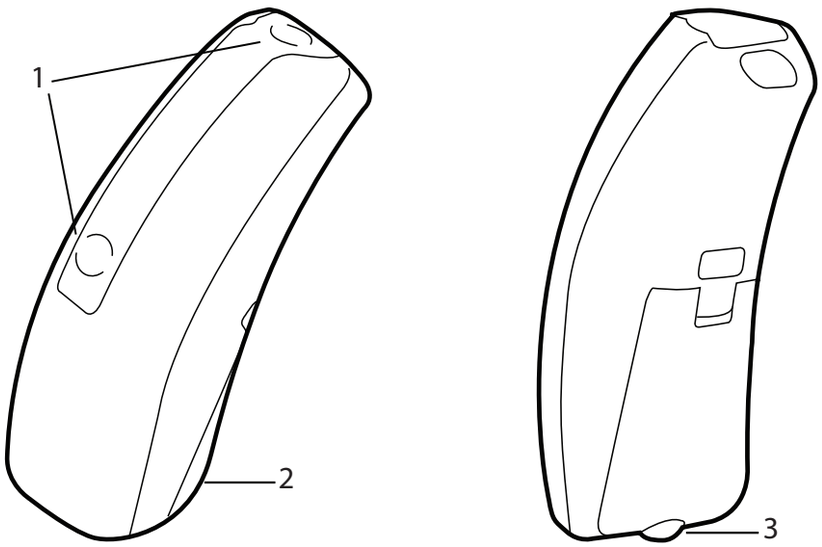
Use your hearing aid regularly, even if it takes some time getting used to it. Infrequent users don't usually get the full benefit of a hearing aid.

NOTE

Your hearing aid and its accessories may not look exactly as illustrated in this booklet. We also reserve the right to make any changes we consider necessary.

Your hearing aid at a glance

The illustration shows your hearing aid without the ear-set. For further information on the ear-set, see the ear-set manual. The ear-set consists of an earwire and an ear-tip, and it is the part of your hearing aid that you wear inside your ear.



1. Microphone openings

2. Battery drawer (on/off function)
3. Nail grip

Important safety information

Read these pages carefully before you begin using your hearing aid.

Hearing aids 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 doctor immediately. In case of ingestion, contact a doctor immediately and the 24 Hour National Button Battery Ingestion Hotline at (202) 625-3333.

Take your hearing aids out when you are not using them. This will help to ventilate the ear canal and prevent ear infections.

Contact your doctor or hearing care professional immediately if you suspect you may have an ear infection.

Remove your hearing aids before showering, swimming or using a hair dryer.

Do not wear your hearing aids when applying perfume, spray, gels, lotion or cream.

 Do not dry your hearing aid in a microwave oven – this will ruin it.

 Never use other people's hearing aids and never allow others to use yours, as this could damage your hearing.

 Never use your hearing aids in environments where there may be explosive gases, such as in mines, etc.

 Keep hearing aids, their parts, accessories and batteries away from children.

 Never try to open or repair the hearing aid yourself. Contact your hearing care professional if you need to have your hearing aid repaired.

Your hearing aids contain radio communication technology. Always observe the environment in which you are using them. If any restrictions apply, you must take precautions to comply with these.

Do not expose your hearing aids to extreme temperatures or high humidity, and dry them quickly if they get wet, or if you perspire heavily.

Your hearing aids should be stored and transported within the temperature and humidity ranges of -18°C to +40°C (-0,4°F to 104°F) and 10%-95% rH.

Storage and transportation up to 60°C (140°F) with 10%-95% rH can be accepted in shorter periods (duration of max. of 2 weeks).

Your hearing aids are designed to operate from 0°C (32°F) to 50°C (122°F).

For more information about your hearing aids, visit: www.widex.com.

THE HEARING AID

Indications for use

The hearing aids are indicated for individuals with a range of hearing loss from slight (16 dB HL) to moderately severe (up to 85 dB HL) and all hearing loss configurations.

They are to be programmed be licensed hearing care professionals (audiologists, hearing aid specialists, otolanryngologists) who are trained in hearing (re)habilitation and tinnitus management.

Intended use

The hearing aids are intended as air conduction amplification devices to be used in everyday listening environments. The hearing aids may be equipped with the Zen program intended to provide

a relaxing sound background (i.e. music/noise source) for adults older than 21 years who desire to listen to such a background in quiet.

The battery

Use a **type 10 zinc-air** battery for your hearing aid.

Always use a fresh, new battery that is precisely the kind recommended by your hearing care professional.

NOTE

Check that the battery is completely clean and free of any residue before inserting it in the hearing aid. Otherwise your hearing aid may not function as expected.

 Never attempt to recharge your hearing aid batteries, as they could explode.

 Never leave a flat battery in the hearing aids while storing them. It could leak and ruin your hearing aid.

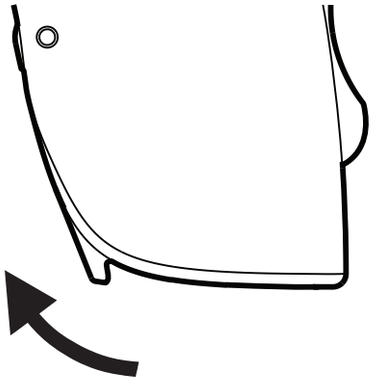
 Dispose of used batteries as indicated on the packaging and take note of the expiry date.

Low battery indication

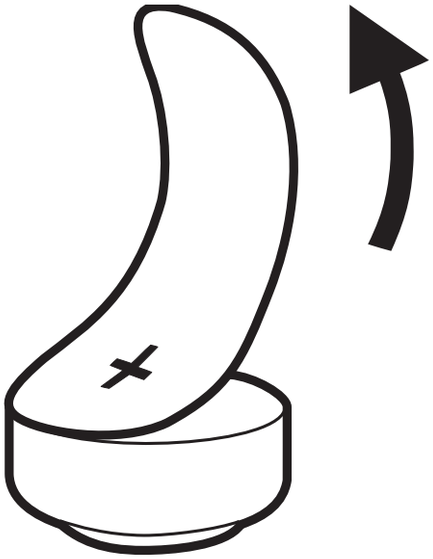
When the battery is weak, a sound signal will play. If the battery drains suddenly there may however be no warning. We recommend carrying a spare battery with you wherever you go.

Changing the battery

To change the battery, do as follows:

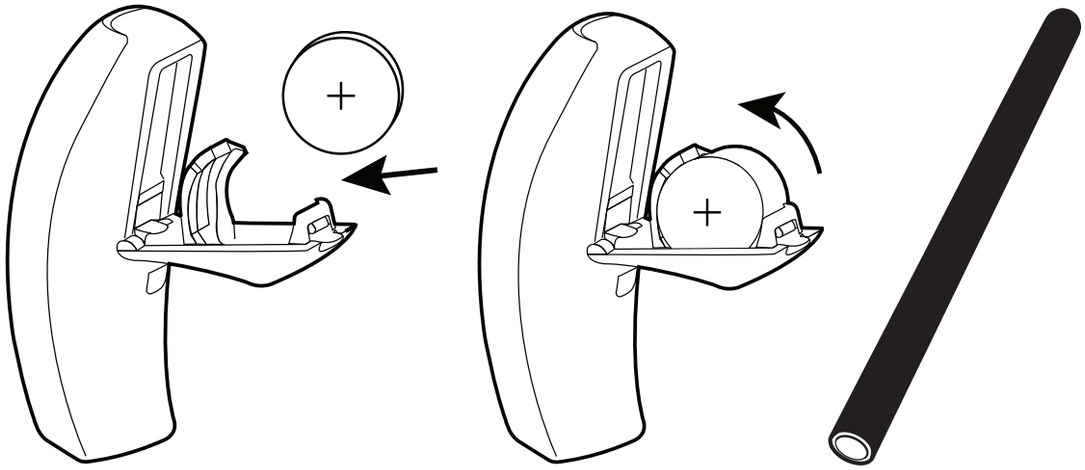


Use the nail grip to gently swing the battery door open and remove the old battery.



Take the adhesive tab off the new battery and make sure there is no sticky substance left on it. Let it "breathe" for 60 seconds.

Now place the new battery in the drawer as shown.



Close the drawer. If it doesn't close easily, the battery is not placed correctly.

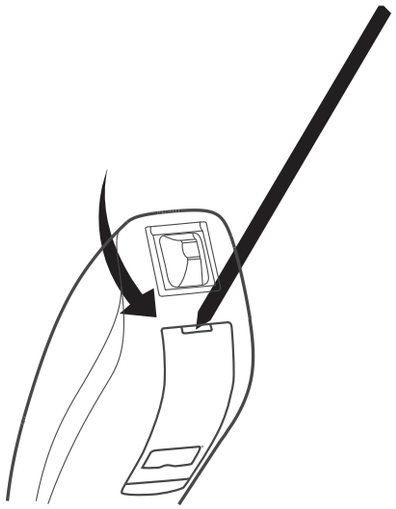
If you are not using the hearing aid for a few days, remove the battery.

NOTE

Avoid dropping your hearing aid – hold the hearing aid above a soft surface while changing the battery.

Tamper-resistant battery drawer

If the hearing aid is going to be used by a child, you can ask your hearing care professional to provide it with a tamper-resistant battery drawer.



To open battery drawer, use the special tool you've received, and do as illustrated.

Sound signals

Your hearing aid plays sounds to inform you that certain features have been activated or that you have changed programs. These sounds may be spoken messages or tones, depending on your needs and preferences.

Program 1	Message/one short beep
Program 2	Message/two short beeps
Program 3	Message or three short beeps
Program 4	Message/one short and one long beep
Program 5	Message/one long beep and two short beeps
Zen+	Message/tone

Ask your hearing care professional to turn these sounds signals off if you don't need them.

Lost partner

(Only available in wireless 440-series)

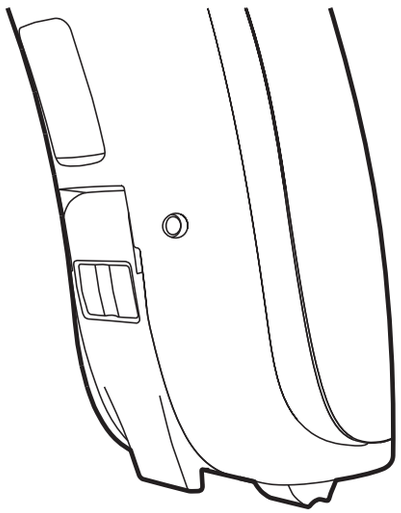
Your hearing care professional can turn on a feature in your hearing aid that warns you whenever it loses contact with the hearing aid in the opposite ear. You will hear a spoken message in your ear.

How to tell right from left

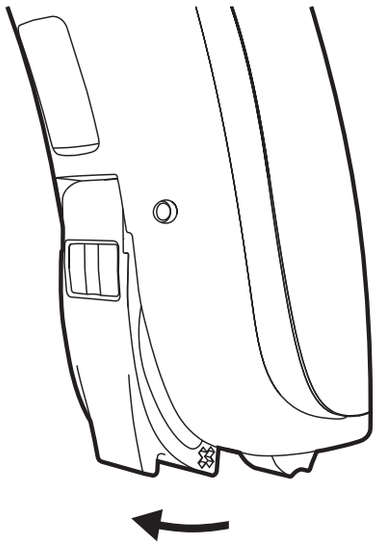
The hearing aid for your right ear has a red mark. The hearing aid for your left ear has a blue mark.

Turning the hearing aid on and off

To turn the hearing aid on, close the battery lid. The hearing aid will play a sound signal to indicate that it is on, unless your hearing care professional has deactivated this function.



To turn off the hearing aid, push the battery lid downwards.



NOTE

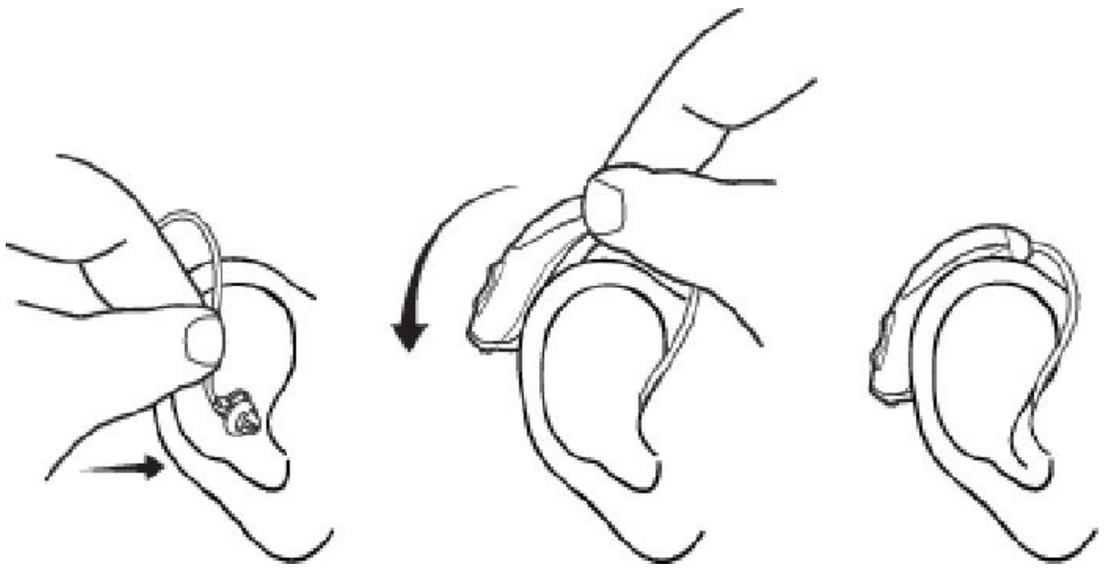
You can also cup the hearing aid in your hand to verify that it is turned on. If it's on, it will whistle.

Don't forget to turn off the hearing aid when it is not in use.

Putting on and removing your hearing aid

Insert the ear-set in the ear while holding the lower part of the tube. Pulling the outer ear upwards and backwards at the same time can be helpful.

Then place the hearing aid behind the ear. The hearing aid should rest comfortably on the ear, close to your head.



Your hearing aid can be fitted using different types of ear-sets. See the separate ear-set manual for more information about your ear-set.

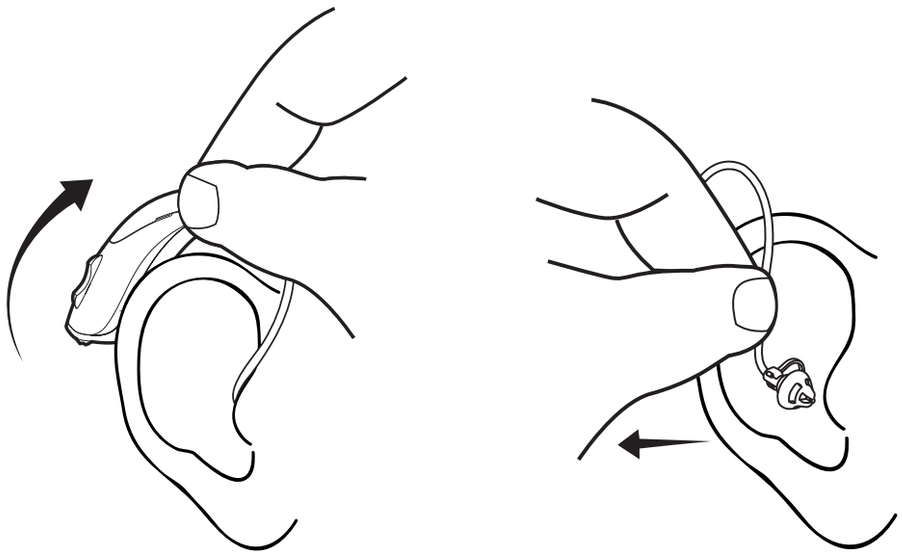
NOTE

If the hearing aid doesn't feel comfortable, or if it doesn't fit properly, causing irritation, redness or the like, contact your hearing care professional.

Removing the hearing aid

Start by removing the hearing aid from behind the ear.

Then take the ear-set carefully out of the ear canal while you hold the lower part of the tube.



Sound adjustment

Your hearing aid adjusts the sound automatically according to your sound environment.

If you have a remote control, you can also adjust the sound manually to achieve more comfort or more audibility, depending on your needs and preferences. For more information on how this works, consult your hearing care professional.

Depending on the hearing aid settings and features, any sound adjustment you make will affect both hearing aids.

Each time you operate the volume control, you will hear a beep-tone unless your hearing care professional has deactivated this function. When you reach the maximum or minimum setting, you will hear a steady tone.

To mute your hearing aid do as follows:

- Keep pressing the lower part of the volume key on the remote control until you can hear the steady sound

To turn the sound on again:

- Press the upper part of the volume key **or**
- Change program

Any adjustment of the volume will be canceled when you turn off your hearing aid or if you change program.

Programs

PROGRAM	USE
Universal	For everyday use
Quiet	Special program for listening in quiet environments
Transport	For listening in situations with noise from cars, trains, etc.
Urban	For listening in situations with changing sound levels (in supermarkets, noisy workplaces or similar)
Party	For listening in situations with many people talking at the same time

PROGRAM	USE
Music	For listening to music
SPECIAL PRO-GRAMS	
Zen	Plays tones or noise for a relaxing sound background. For more information, see under "The Zen program"
Phone	This program is designed for listening to phone conversations
Zen+	This program is similar to Zen but allows you to listen to different types of tones or noise

Depending on your hearing loss, your hearing care professional can activate the Audibility Extender feature. Ask your hearing care professional if you could benefit from this.

If your needs and preferences change over time, your hearing care professional can easily change your program selection

Changing programs

To change programs, simply push the program key on your remote control.

Zen+

To access this program, press and hold the program key for more than one second. A quicker press then allows you to cycle through the available Zen styles. To exit the program, press and hold down the program key for more than one second.

The Zen program

Your hearing aid may be provided with a unique optional listening program called Zen.

Indication for use

The Zen program is intended to provide a relaxing sound background (i.e., music/noise source) for adults 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 prescribed by a hearing care professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

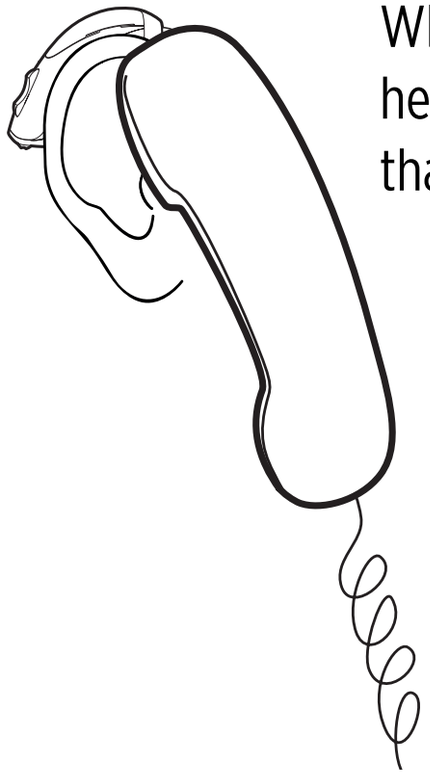
Directions for use

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

CAUTION

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

Using a phone with hearing aids

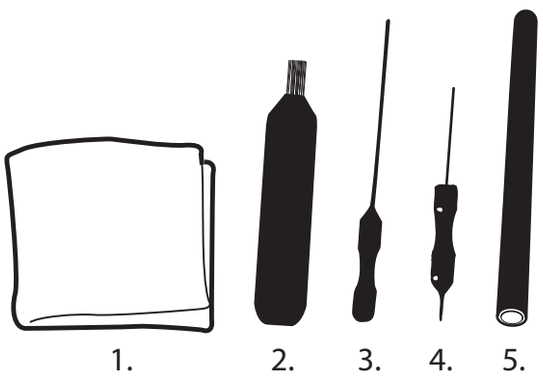


When you use a phone, hold it against your head at an angle above your ear, rather than directly against the ear.

CLEANING

Tools

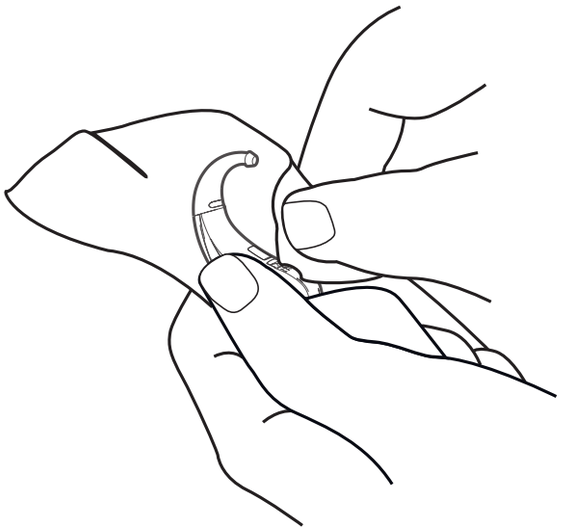
You will receive the following cleaning tools with your hearing aid.



1. Cloth
2. Brush
3. Long wax removing tool
4. Short wax removing tool
5. Battery magnet

Cleaning the hearing aid

Cleaning your hearing aid every day will make it more efficient and more comfortable to wear.



Wipe the hearing aid with a soft cloth (for example the cloth you received from your hearing care professional).

If the microphone openings are still blocked, contact your hearing care professional.

Dry your hearing aid quickly if it gets wet, or if you perspire heavily. Some people use a special dehumidifier like Widex Dry-Go to help keep their hearing aids dry and clean. Ask your hearing care professional if this is right for you.

Leave the battery compartment open to ventilate the hearing aid.

For information on how to clean your ear-set, see the ear-set manual.

Do not use any kind of liquid or disinfectant to clean your hearing aid.

Clean and inspect your hearing aid every day after use to check that it is not broken. If the hearing aid breaks while you are wearing it, leaving small fragments in your ear canal, contact your doctor. Never try to take out the fragments yourself.

ACCESSORIES

You can use a variety of accessories with your hearing aid. To see whether you could benefit from using these accessories, ask your hearing care professional.

Name	Use
RC-DEX	remote control
TV-DEX	for listening to TV and audio
PHONE-DEX*	for easy landline use
FM+DEX	for streaming audio and FM signals
UNI-DEX	for connecting hearing aids to mobile phones

Name	Use
CALL-DEX	for easy wireless connection to mobile phones
COM-DEX	for wireless connection to mobile phones and other devices via bluetooth

*Available in some countries only.

TROUBLESHOOTING

These pages contain advice on what to do if your hearing aid stops working or if it doesn't work as expected. If the problem persists, contact your hearing care professional.

Problem	Possible cause	Solution
The hearing aid is completely silent	It is not turned on	Make sure the battery drawer is completely closed
The battery does not work	Insert a new battery	

Problem	Possible cause	Solution
The hearing aid volume is not powerful enough	Your ear is blocked by earwax	Contact your doctor
Your hearing may have changed	Contact your hearing care professional/ doctor	
The hearing aid whistles continuously	Your ear is blocked by earwax	Contact your doctor
Your two hearing aids are not working in synchrony	The connection between the hearing aids is lost	Turn them off and on again

Problem	Possible cause	Solution
The hearing aids do not respond with a corresponding change in volume or program to the control device	a. The device is used beyond the transmission range b. Strong electromagnetic interference in the vicinity c. The device and the hearing aids are not matched	a. Move the device closer to the hearing aids. b. Move away from known source of EM interference c. Check with your hearing care professional to make sure the device is matched with hearing aids

Problem	Possible cause	Solution
You hear “interrupted” speech (on and off) from the hearing aids or no speech (muted) from the transmitting hearing aid.	a. The battery in one of the hearing aids has expired b. Strong electromagnetic interference in the vicinity	a. Replace battery in one or both hearing aids b. Move away from known sources of interference

NOTE

This information covers only the hearing aid. See the “Ear-sets for Widex hearing aids” user manual for information specific to your ear-set. If the problems persist, contact your hearing care professional for assistance.

REGULATORY INFORMATION

The following Table summarizes the technical details of the WidexLink technology as it is implemented in the UNIQUE™ hearing aids.

	Hearing aids	RC-DEX	TM-DEX	Bluetooth* - NOAHlink
Antenna type	Inductive antenna	Inductive antenna	Inductive antenna	Embedded ceramic antenna

	Hearing aids	RC-DEX	TM-DEX	Blue-tooth* - NOAHlink
Antenna dimen-sions	Ø1.8 mm, L - 4.85 mm	Ø8 mm, L – 20 mm	Ø6 mm, L - 8 mm	NA
Modula-tion	FSK	FSK	FSK	FHSS/ GFSK, π/4 DPSK, 8 DPSK

	Hearing aids	RC-DEX	TM-DEX	Blue-tooth* - NOAHlink
Magnetic Field Strength (at 10 m distance)	-54 dBµA/m	-13 dBµA/m	-26 dBµA/m	NA
Output power (EIRP**)	29 pW	21 nW	1.2 nW	+4dB re. 1mW

	Hearing aids	RC-DEX	TM-DEX	Blue-tooth* - NOAHlink
Range	< 1 m remote unit to hearing aid < 30 cm between hearing aids or Hearing aid to TM-DEX	< 1 m remote unit to hearing aid	< 30 cm between hearing aid and TM-DEX	< 10 m between PC and - NOAHlink

	Hearing aids	RC-DEX	TM-DEX	Blue-tooth* - 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
Bandwidth	660 kHz (-15 dB)	660kHz (-15 dB)	660kHz (-15 dB)	1 MHz

	Hearing aids	RC-DEX	TM-DEX	Blue-tooth* - NOAHlink
Data-rate	212 kbit/ second (raw chan-nel capaci-ty)	212 kbit/ second (raw chan-nel capaci-ty)	212 kbit/ second (raw chan-nel capaci-ty)	2.1 Mbps
Data flow	Simplex or semi-du-plex capa-bility	Simplex capability	Simplex or semi-du-plex capa-bility	Time divi-sion du-plex (TDD)

	Hearing aids	RC-DEX	TM-DEX	Blue-tooth* - NOAHlink
Protocol	Random Access – no collision avoidance	Random Access – no collision avoidance	Random Access – no collision avoidance	Packet-based protocol, time divi-ded; se-cure Serial Port Pro-file (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 hearing aid functions. The UNIQUE wireless hearing aids share input information between the two partner hearing aids. In so doing, the wearers would experience the following additional user benefits (only when wearing binaural UNIQUE hearing aids).

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

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

Surveillance of partner hearing aid – The hearing aid(s) will signal an alert (“partner check”) when a hearing aid battery has expired, or that one of the hearing aids has fallen off. In rare instances, a much stronger wireless source nearby may activate this alert. This serves as an early warning to the wearer of such service interruption.

Coordination of compression – The UNIQUE hearing aids maintain the intensity level difference between ears (inter-aural level difference, ILD). In some situations where speech is presented to one side and noise the other side, this coordinated action could enhance the relative loudness of the speech sounds to the noise background and improve speech understanding for some wearers.

More accurate identification of feedback – The UNIQUE hearing aids distinguish between “true” hearing aid whistling (or feedback) and music sounds to prevent unnecessary feedback cancellation and preserve natural sound quality.

(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

Radio transmitter / cables / transducers

The UNIQUE™ series hearing aid 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 dBµA/m @ 10 m

Duty Cycle: < 5 % (averaged over 1 hour of operation)

Simplex or semi duplex capability

The radio receiver in the UNIQUE™ series hearing aid 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 UNIQUE™ series hearing aid nor during programming of the hearing aid.

Quality of Service for Wireless Technology in the WidexLink System

WidexLink wireless technology enables communication between two partners of a binaural pair of UNIQUE hearing aids 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 hearing aid even when transmission is interrupted.

During daily use, the requirements on audio streaming between hearing aids 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 hearing aids, a BER better than 10-3 is required. The communication is updated every 50 ms (or 20 Hz). The hearing aids continue to amplify 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 UNIQUE™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a UNIQUE™ series hearing aid should assure that it is used in such an environment.

Emissions test	Compli-ance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The UNIQUE™ hearing aid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The UNIQUE™ hearing aid is suitable for use in all establishments, includ-ing domestic establishments and those directly connected to the pub-lic low – voltage power supply net-work that supplies buildings used for domestic purposes.

Harmonic emissions IEC 61000-3-2	Not applica-ble *)	
Voltage fluc-tuations/ flicker emis-sions IEC 61000-3-3	Not applica-ble *)	

*) Battery powered equipment

Electromagnetic immunity

The UNIQUE™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a UNIQUE™ series hearing aid should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compli- ance level	Electromagnet- ic environment – guidance
Immunity Test	IEC 60601 Test level	Compli- ance level	Electromagnet- ic environment – guidance

Immunity Test	IEC 60601 Test level	Compli-ance level	Electromagnet-ic environment – guidance
Electrostatic dis-charge (ESD) IEC 61000-4-2	± 6 kV con-tact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, con-crete or ceram-ic tile. If floors are covered with synthetic material, the relative humidi-ty should be at least 30%.

Immunity Test	IEC 60601 Test level	Compli-ance level	Electromagnet-ic environment – guidance
Electrical fast transients/burst IEC 61000-4-4	± 2 kV for power line supplies ± 1 kV for in-put/output lines	Not applicable *) Not applicable *)	Not applicable *)

Immunity Test	IEC 60601 Test level	Compli- ance level	Electromagnet- ic environment – guidance
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	Compli- ance level	Electromagnet- ic environment – guidance
Voltage dips, short interrup- tions and volt- age variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT	Not applicable *)	Not applicable *)

Immunity Test	IEC 60601 Test level	Compli- ance level	Electromagnet- ic environment – guidance
	(30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s		

Immunity Test	IEC 60601 Test level	Compli-ance level	Electromagnet-ic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequen-cy magnetic fields should be at levels char-acteristic of a typical location in a typical commercial or hospital envi-ronment
NOTE UT is the a.c. mains voltage prior to the application of the test level.			

*) Battery powered equipment

Electromagnetic immunity – cont.

The UNIQUE™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a UNIQUE™ series hearing aid should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compli- ance level	Electromagnetic environment – guidance

			Portable and mobile RF communications equipment should be used no closer to any part of the UNIQUETM series hearing aid, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance d = 1.2 ÖP
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 ÖP 80 MHz to 800 MHz d = 2.3 ÖP 800 MHz to 2.5 GHz

Immunity Test	IEC 60601 Test level	Compli-ance level	Electromagnetic environment – guidance

			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). 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. Interference may occur in the vicinity of equipment marked with the following symbol:

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 UNIQUE™ series hearing aid is used exceeds the applicable RF compliance level above, the UNIQUE™ series hearing aid 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 UNIQUE™ series hearing aid.

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 UNIQUE™ series hearing aids.

The UNIQUE™ series hearing aids are intended for use in the electromagnetic environment in which RF disturbances are controlled. The customer or the user of the UNIQUE™ series hearing aid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UNIQUE™ hearing aids 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 ÖP	80 MHz to 800 MHz d = 1.2 ÖP	800 MHz to 2.5 GHz d = 2.3 ÖP
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 UNIQUE™ hearing aid may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements.

(EMI/EMC Compliance).

The UNIQUE™ hearing aid 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 300 330-2 V1.5.1	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- 13:2011	Immunity RF Near Field immunity test	International Product std. for hearing aids to ensure adequate immunity to radio interference from cell telephones.
ANSI C63.19-2007	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 per-

sonal 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 and IC statements and EC directives

FCC ID: TTY-UPA

IC: 5676B-UPA

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.

EC directives

Directive 1999/5/EC

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

A copy of the Declaration of Conformity according to 1999/5/EC can be found at:

http://widex.com/doc


N26346

Information regarding disposal

Electrical and electronic equipment (EEE) contains materials, components and substances that can be hazardous and present a risk to human health and the environment when waste electrical and electronic equipment (WEEE) is not handled correctly.

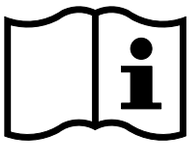
Do not dispose of hearing aids, hearing aid accessories and batteries with ordinary household waste. (Continues on next page).

(Continued) Hearing aids, batteries and hearing aid accessories should be disposed of at sites intended for waste electrical and electronic equipment, or given to your hearing care professional for safe disposal. Proper disposal helps to protect human health and the environment.

SYMBOLS

Symbols commonly used by Widex A/S in medical device labelling (labels/IFU/etc.)

Symbol	Title/Description
	**Manufacturer** The product is produced by the manufacturer whose name and address are stated next to the symbol. If appropriate, the date of manufacture may also be stated.
	**Catalog number** The product's catalog (item) number.

Symbol	Title/Description
	**Consult instructions for use** The user instructions contain important cautionary information (warnings/precautions) and must be read before using the product.
	**Warning** Text marked with a warning symbol must be read before using the product.

Symbol	Title/Description
	**WEEE mark** “Not for general waste” When a product is to be discarded, it must be sent to a designated collection point for recycling and recovering to prevent the risk of harm to the environment or human health as a result of the presence of hazardous substances.
CE	**CE mark** The product is in conformity with the requirements set out in European CE marking directives.

Symbol	Title/Description
	**RCM mark** The product complies with electrical safety, EMC and radio spectrum regulatory requirements for products supplied to the Australian or New Zealand market.
	**Interference** Electromagnetic interference may occur in the vicinity of the product.

WIDEX A/S

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