WIDEX **BEYOND**™

USER INSTRUCTIONS
THE WIDEX BEYOND™ HEARING AID

B-F2 model
RIC/RITE
Receiver-in-canal/Receiver-in-the-ear

WIDEX®
HIGH DEFINITION HEARING

YOUR HEARING AID

(To be filled out by the hearing care professional)

Your hearing aid series:

PROGRAMS	
☐ Universal	☐ Audibility Extender
☐ Quiet	☐ Audibility Extender
☐ Transport	☐ Audibility Extender
☐ Urban	☐ Audibility Extender
☐ Party	☐ Audibility Extender
☐ Music	☐ Audibility Extender
☐ T	☐ Audibility Extender
☐ T	☐ Audibility Extender

SPECIAL PROGRAMS	
☐ Zen	☐ Audibility Extender
☐ Phone	☐ Audibility Extender

SMARTTOGGLE PROGRAMS

☐ Zen+	☐ Audibility Extender
☐ Phone+	☐ Audibility Extender

NOTE

The description and use of the Phone and Phone+ programs in this user guide refer only to normal phone conversations, not phone conversations using direct streaming from your smartphone.

NOTE

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

NOTE

This hearing aid allows direct wireless control and sound streaming from smartphones and other devices. For more help and information contact your hearing care professional or visit www.widex.com/BEYOND.

This hearing aid works wirelessly with the Beyond App. We take no responsibility if the hearing aid is used with any third part App or if the Beyond App is used with any other device.

CONTENTS

YOUR HEARING AID

Welcome

Congratulations on your new hearing aid.

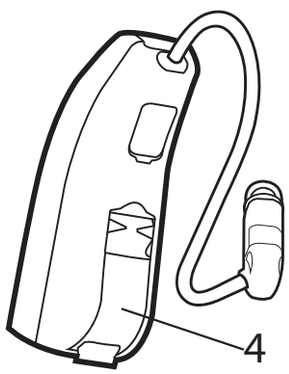
Use your hearing aid regularly, even if it takes some time getting used to it. Infrequent users don't usually get the full benefit of a hearing aid.

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

1. Push button
2. Nail grip
3. Earwire



4. Battery compartment

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 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.

Please note that streaming sound to your hearing aids at a high volume can prevent you from hearing other important sounds such as alarms and traffic noise. In such situations make sure to keep the volume of the streamed sound at a suitable level.

Your hearing aid is very powerful and it can play sounds that exceed a level of 132 dB. There may therefore be a risk of damaging your remaining hearing.

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 -20°C to +55°C (-4°F to 131°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 minimal (10dB HL) to severe-to-profound (100 dB HL)] and all hearing loss configurations.

They are to be programmed by licensed hearing care professionals (audiologists, hearing aid specialists, otolaryngologists) 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 312 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.

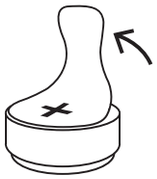
Dispose of used batteries as indicated on the packaging and take note of the expiry date.

Low battery indication

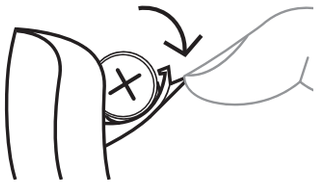
When the battery is weak, a sound signal will play. If the battery drains suddenly there may however be no warning. We recommend carrying a spare battery with you wherever you go.

Changing the battery

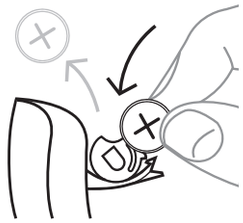
To change the battery, do as follows:



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.



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



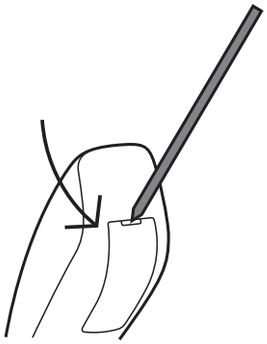
Now place the new battery in the drawer as shown. Close the drawer. If it doesn't close easily, the battery is not placed correctly.
If you are not using the hearing aid for a few days, remove the battery.

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 door.



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 can be spoken messages or tones.

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

Lost partner

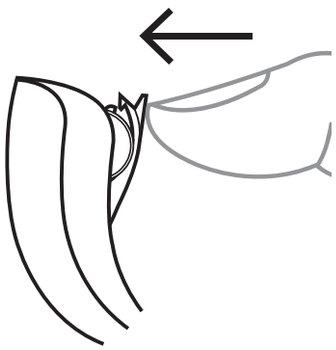
(Only available in 440-series)

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.

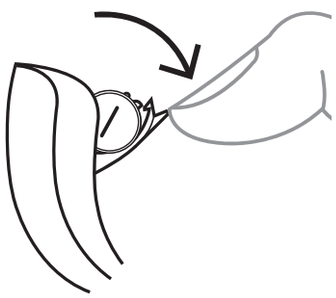
How to tell right from left

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 drawer. 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 drawer downwards.

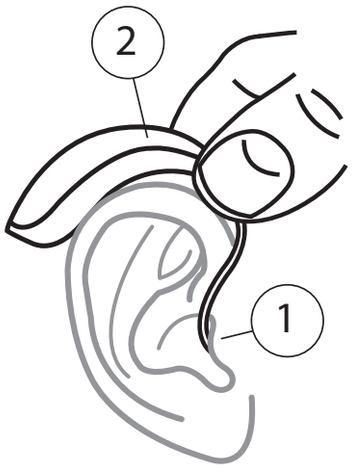
NOTE

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 the hearing aid

To put on your hearing aid:



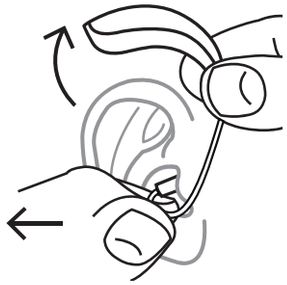
1. Insert the ear-set in the ear while holding the lower part of the tube. Pulling the outer ear upwards and backwards at the same time can be helpful.
2. Then place the hearing aid behind the ear. The hearing aid should rest comfortably on the ear, close to your head.

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.

Programs

PROGRAMS	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
Music	For listening to music
T	With this program you listen through the hearing aid's telecoil, which allows you to listen directly to the sound without background noise (requires a teleloop system)

PROGRAMS	USE
M+T	This program is a combination of the hearing aid's microphone and the telecoil. You listen to the sound source, but can also hear other sounds

SPECIAL PROGRAMS	USE
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

SMARTTOGGLE PROGRAMS	USE
Zen+	This program is similar to Zen but allows you to listen to different types of tones or noise
Phone+	This program is designed for listening to phone conversations

NOTE

The names in the list of programs are the default names. Your hearing care professional can also select a program name from a preselected list. Then it is even easier for you to select the right program in each listening situation.

NOTE

You can only have one SmartToggle program on your hearing aid.

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.

The Zen program

Your hearing aid may be provided with a unique optional listening program called Zen. It makes musical tones (and sometimes a rushing noise) in the background. The Zen program may be used alone (without amplification) in quiet when you are not required to hear surrounding sounds. Or, it may be used with amplification so that both the surrounding sounds and the generated sounds (fractal tones and noise) are heard together.

CAUTION

Use of the different Zen programs may interfere with hearing surrounding sounds including speech. The programs should not be used when hearing such sounds is important. Switch the hearing aid to a non-Zen program in those situations.

The duration of the Zen play time can be set by your hearing healthcare professional according to your needs.

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.

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 healthcare professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

Directions for use

The Zen program can be activated with a simple push of the program button on the hearing aid (or on the remote control). Depending on how your hearing care professional has set up the program, you can access the Zen program by a "short-press" of the program button or a "long-press" of the program button.

- "Short-press" option - the program button is pressed for less than a second. At most two listening programs can be programmed for Zen.
- "Long-press" option - the program button is pressed and held for more than 1 second. Up to three Zen styles are available. A "short-press" of the program button in the long-press mode will allow you to cycle through the available Zen styles. You can exit the "long-press" mode by pressing and holding the program button for more than one second.

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.

Precautions

To ensure the safety and effectiveness of the Zen program 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 hearing aid and the Zen program according to the directions and schedule recommended by your hearing care professionals.

Contraindications

The following symptoms are contraindicated for the use of hearing aids. Including the Zen program

- 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

Warnings

Use of the Zen program may interfere with hearing everyday sounds including speech. It should not be used when hearing such sounds is important. Switch the hearing aid to a non-Zen program in those situations.

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 hearing aids (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

Sound and program adjustment

If you have two hearing aids, the push button can be programmed in several ways:

As a dedicated program button:

To change programs, just tap the button. To access and exit SmartToggle programs, push and hold the push button down for more than one second (this setting is optional). Once you have accessed the SmartToggle program, you can change among the different Zen styles by short taps on the button.

As a dedicated sound adjustment button:

Tap the button on your right hearing aid if you'd like more audibility and more volume. If you need to decrease the volume or you'd like more comfort, tap the button on your left hearing aid.

A long push on either of your hearing aids will mute and unmute the sound (this setting is optional).

As a combined program and sound adjustment button:
If you have this option, tap the button on your right hearing aid if you'd like more audibility and more volume. If you need to decrease the volume or if you'd like more comfort, just tap the button on your left hearing aid. A long push on either of your hearing aids will change programs.

If you only have one hearing aid, a short tap will change programs and a long tap will allow you to access the SmartToggle programs.

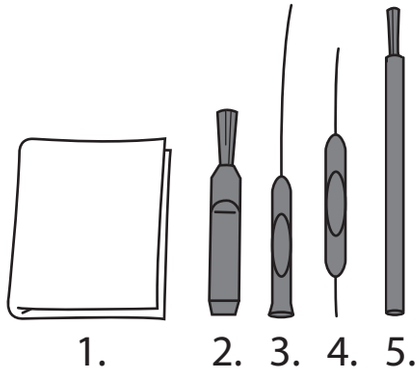
Using a phone with your hearing aids

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 UV to help keep their hearing aids dry and clean. Ask your hearing care professional if this is right for you.

When not in your ears 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
T-DEX	for connecting hearing aids to mobile phones via a telecoil
UNI-DEX	for connecting hearing aids to mobile phones
CALL-DEX	for easy wireless connection to mobile phones
COM-DEX	for wireless connection to mobile phones and other devices via bluetooth
COM-DEX Remote Mic	for helping hearing aid users hear speech in difficult listening situations

Available in some countries only.

Compatibility with smartphones

You can see a list of compatible smartphones, tablets, etc, at:

www.widex.com/BEYOND

You can also use this QR code:

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
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
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 is dead 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 and BTLE (Bluetooth Low Energy) technologies as they are implemented in the BEYOND™ hearing aids.

	Hearing aids		RC-DEX	TM-DEX	Bluetooth* - NOAHlink
	Wlink	BTLE			
Antenna	Integral Inductive antenna	Integral antenna	Integral Inductive antenna	Integral Inductive antenna	Embedded ceramic antenna
Modulation	FSK	GFSK	FSK	FSK	FHSS/GFSK π/4 DPSK, 8 DPSK
Magnetic Field Strenght (at 10 m distance)	-54 dBµA/m	N/A	-13 dBµA/m	-26 dBµA/m	N/A
Radiated output power (EIRP**)	-29 pW	1 mW (0 dBm)	21 nW	1.2 nW	+4dB re. 1mW

	Hearing aids		RC-DEX	TM-DEX	Bluetooth* - NOAHlink
Range	<1 m remote unit to hearing aid <30 cm between hearing aids or hearing aid to TM-DEX	5 m	< 1 m remote unit to hearing aid	< 30 cm between hearing aid and TM-DEX	< 10 m between PC and NOAHlink
Center frequency	10.6 MHz	2.484 GHz	10.6 MHz	10.6 MHz	2.441 GHz
Frequency range	10.2 - 11.0 MHz	2.402 - 2.478 GHz	10.2 - 11.0 MHz	10.2 - 11.0 MHz	2.402 - 2.480 GHz
Frequency Bandwidth	660 kHz (-15 dB)	2 MHz	660 kHz (-15 dB)	660 kHz (-15 dB)	1 MHz
Channel	Single channel radio	40 Channels	Single channel radio	Single channel radio	5 logical channels
Duty Cycle***	< 5 %	< 5 %	< 5 %	< 5 %	< 5 %

	Hearing aids		RC-DEX	TM-DEX	Bluetooth* - NOAHlink
Data-rate	212 kbit/ second (raw channel capacity)	1 Mbps	212 kbit/ second (raw channel capacity)	212 kbit/ second (raw channel capacity)	2.1 Mbps
Data flow	Simplex or semi-duplex capability	Time division duplex (TDD). Semiduplex	Simplex capability	Simplex or semi-duplex capability	Time division duplex (TDD)
Protocol	Random Access - no collision avoidance	Packet - based protocol, time divided	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.

*** Averaged over 1 hour of operation
The radio receivers in the BEYOND™ series hearing aid are using the same frequencies and bandwidth as the corresponding transmitters.

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 BEYOND 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 BEYOND 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 BEYOND 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 BEYOND hearing aids distinguish between “true” hearing aid whistling (or feedback) and music sounds to prevent unnecessary feedback cancellation and preserve natural sound quality.

Radio transmitter / cables / transducers

The BEYOND™ series hearing aid contains a radio transmitter / receiver with the following

Cables and transducers:
No cables and transducers are used neither during normal use of the BEYOND™ 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 BEYOND 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 require-

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BEYOND™ 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 BEYOND™ hearing aid 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 immunityThe BEYOND™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a BEYOND™ series hearing aid should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
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 *)

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	Not applicable *)	Not applicable *)
	± 2 kV line(s) to earth	Not applicable *)	
Voltage dips, short interruptions and voltage 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 (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable *)	Not applicable *)

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
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 UT is the a.c. mains voltage prior to the application of the test level.			

*) Battery powered equipment
Electromagnetic immunity – cont.

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

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BEYONDTM series hearing aid, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

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	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

Immunity Test	IEC 60601 Test level	Compliance 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.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			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.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance

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

The BEYOND™ series hearing aids are intended for use in the electromagnetic environment in which RF disturbances are controlled. The customer or the user of the BEYOND™ series hearing aid can help prevent electromagnetic interference by maintaining a minimum distance between portable

and mobile RF communications equipment (transmitters) and the BE-YOND™ 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 $d = 1.2 \sqrt{P}$	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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)

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 BEYOND™ hearing aid may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements. (EMI/EMC Compliance).
The BEYOND™ 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.

Standard	Test type	Note
EN 300 328 V1.9.1	RF emissions incl Spurious emissions	EMC and radio spectrum matters for wideband data transmission systems in the 2.4 GHz ISM band
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 V1.6.1	Immunity, RF and ESD	Standard for Low Power Transmitters in the frequency range 9 kHz – 40 GHz
EN 301 489-17 V2.2.1	Immunity, RF and ESD	EMC Standard for broadband data transmission systems

Standard	Test type	Note
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.

Warning to hearing aid dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 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.
Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user.

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.

EC directives

Directive 1999/5/EC

Hereby, Widex A/S declares that this B-F2 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

Do not dispose of hearing aids, hearing aid accessories and batteries with ordinary household waste.

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.

FCC and IC statements

FCC ID: TTY-BF2

IC: 5676B-BF2

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.

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.
	**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.
	**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.

Symbol	Title/Description
CE	**CE mark** The product is in conformity with the requirements set out in European CE marking directives.
	**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.

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