

WIDEX **MOMENT™**

USER INSTRUCTIONS

THE WIDEX MOMENT™ FAMILY

MRRLD model
RIC/RITE
(Receiver-in-canal/Receiver-in-the-ear)



WIDEX

SOUND LIKE NO OTHER

IMPORTANT SAFETY INFORMATION

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



WARNING: People younger than 18 should go to a doctor before using this. People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.



WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine 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:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months

- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz



WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL: You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.



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.



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



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.



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 or an allergic reaction.



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



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



Do not wear your hearing aids when applying perfume, spray, gel, 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.



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.



Your device has been designed to comply with international electromagnetic compatibility standards. However, there is still the possibility that it may cause interference with other electrical equipment. If you experience interference, keep a distance to other electrical equipment.



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.



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 is damaged while you are wearing it and small fragments are left in your ear canal, seek medical attention. Never try to take out the fragments yourself.



Note that any unauthorized changes to the product may cause damage to the product or cause injury.

- Use only approved parts and accessories. Ask you Hearing Care Professional for support.
- Do not modify this equipment without authorization from the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure safe use of the equipment.

NOTE

In case of a serious incident, report the occurrence to the manufacturer of the device.



Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.



Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.



Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can.

You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.



Note: What you might expect when you start using a hearing aid.

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.



Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.



Note: Hearing loss in people younger than 18.

- People younger than 18 should see a doctor first, preferably an ear-nose-throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid.

The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

YOUR HEARING AID

(To be filled out by your hearing care professional)

This is a list of possible programs for your hearing aid.

For further information on the use of these programs, see Customization.

Your hearing aid programs:

PROGRAMS	AUDIBILITY EXTENDER
☐ Universal	☐
☐ PureSound	☐
☐ Quiet	☐
☐ Comfort	☐
☐ Transport	☐
☐ Urban	☐
☐ Impact	☐
☐ Party	☐
☐ Social	☐
☐ Music	☐

SPECIAL PROGRAMS**AUDIBILITY EXTENDER**☐ Zen/Relax☐☐ Phone☐**SMARTTOGGLE PROGRAMS****AUDIBILITY EXTENDER**☐ Zen+/Relax+☐

The program names in the table are the default names. If you have chosen to use some of the other names available, write the new names in the table. That way you will always know which programs you have in your hearing aids.

Read the instructions

Carefully read the user instructions in this booklet and in the booklet "Ear-sets for Widex hearing aids" before you start using your hearing aid. You should also read the user instructions for the charger.

Sound streaming and wireless control

The hearing aid allows sound streaming and direct wireless control from smartphones and other devices via DEX. For more help and information contact your hearing care professional or visit: www.widex.com.

The hearing aid works wirelessly with the MOMENT app. We take no responsibility if the hearing aid is used with any third party app or if the app is used with any other device. Read more about the app in the booklet.

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YOUR HEARING AID

Welcome

Congratulations on your new hearing aid.

This hearing aid is powered by a rechargeable lithium-ion battery and must be used with the charger model WPP401. The battery is built-in and you cannot replace this.

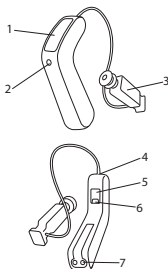
We recommend that you use your hearing aid regularly, even if it takes some time getting used to it. Infrequent users do not usually get the full benefit of a hearing aid.

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.

The hearing aid at a glance

Your hearing aid is shown below – in the first illustration with the ear-set. The ear-set consists of an earwire with receiver and an ear-tip, and it is the part of your hearing aid that you wear inside your ear.



1. Microphone grid
2. Light indicators
3. Earwire with receiver
4. Earwire connection
5. Identification plate (model and serial number)
6. Left/right identification
7. Charging contacts

The colour of the left/right identification tells you how to know left from right. The hearing aid for your left ear has a blue mark. The hearing aid for your right ear has a red mark.

For further information on the ear-set, see the ear-set manual.

CONDITIONS FOR USE

Indications for use

The hearing aids are indicated for individuals older than 36 months with a range of hearing loss from minimal (0 dB HL) to severe (110 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.

Hearing aids with rechargeable batteries

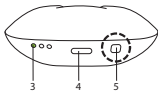
Hearing aids with rechargeable batteries should NOT be used by children younger than 36 months or mentally disabled people.

Intended use / Intended purpose

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 who desire to listen to such a background in quiet.

Charging

We recommend that you charge your hearing aid daily. This illustration shows your charger at a glance:



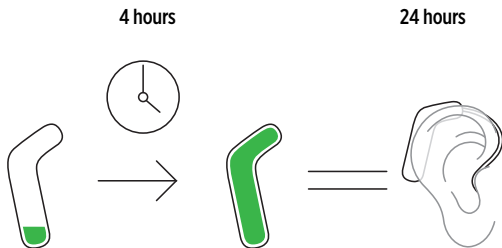
1. Charging wells
2. Cover
3. Light indicators
4. USB-C port
5. On/Off button

For further information on how to charge your hearing aid, see the user instructions for the charger.

Use time and charging time

If you charge your hearing aid for half an hour, you have approximately 4 hours of use. Charging your hearing aid fully will take approximately 4 hours.

When the hearing aid is fully charged, you can use it for at least 24 hours in normal hearing environments before the next charge.



When you hear the battery alarm indicating low power, you will have approximately 3-4 hours of normal use. The hearing aid turns off when the battery power is critically low.

Hearing loss, sound environment and streaming are factors that affect the estimated use time. For example, if you use the streaming service, you will reduce the use time of the hearing aid.

Operating and charging conditions

Your hearing aid has been designed to operate in everyday situations, and it works in environmental conditions that are comfortable for you. You can wear your hearing aid during flights, but you should remove it before showering, swimming and sleeping.

Operating conditions

	Minimum	Maximum
Temperature	0 °C (32 °F)	50 °C (122 °F)
Humidity	10% rH	95% rH
Atmospheric pressure	750 mbar	1060 mbar

Charging conditions

	Minimum	Maximum
Temperature	10 °C (50 °F)	35 °C (95 °F)
Humidity	20% rH	75% rH

Long-term storage when not in use

If you plan to not wear your hearing aids for a longer period of time, they need to be stored in the charger for being kept turned off during long-term storage when not in use.

Every 6 months you will have to charge the hearing aid to avoid an unrecoverable deep-discharge of the battery. A deep-discharged battery can no longer be charged and has to be replaced. We would however recommend recharging more frequently than every 6 months.

Storage and transport conditions

Your hearing aid is sensitive to extreme conditions such as high temperatures. It should not be stored or transported in direct sunlight, but only within the following conditions.

Storage conditions		
	Minimum	Maximum
Temperature	10 °C (50 °F)	40 °C (104 °F)*
Humidity	20% rH	90% rH

*Recommended temperature is 10°C to 25°C.

Transport conditions

	Minimum	Maximum
Temperature	-20 °C (-4 °F)	55 °C (131 °F)
Humidity	10% rH	90% rH

You can find technical data sheets on www.widexpro.com/documents and additional information on your hearing aids on www.widex.com.

DAILY USE

Turning the hearing aid on and off

Turning on the hearing aid:

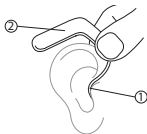
- Remove the hearing aid from the charger, and it turns on automatically after a few seconds. The hearing aid will play a sound signal to indicate that it is on.

Turning off the hearing aid:

- Place the hearing aid in the charger and the charging starts.

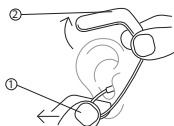
Putting on and removing the hearing aid

Putting on the hearing aid



1. Insert the ear-set into the ear while holding the lower part of the earwire. 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.

Removing the hearing aid



1. Start by removing the hearing aid from behind the ear.
2. Then take the ear-set carefully out of the ear canal while you hold the lower part of the earwire.

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.

Operating the hearing aid

To change program or to adjust the volume control, use your app or your remote control.

CUSTOMIZATION

Programs

This is an overview of programs that you can select from. Ask your hearing care professional for guidance.

PROGRAMS	USE
Universal	Automatic program with focus on optimum sound in all situations
PureSound	Automatic program with focus on natural and pleasant sound in all situations
Quiet	Special program for listening in quiet environments
Comfort	Special program for listening in noisy environments
Transport	For listening in situations with noise from cars, trains, etc.
Impact	Use this program if you prefer a clear and sharp sound
Urban	For listening in situations with changing sound levels (in supermarkets, noisy workplaces or the like)

PROGRAMS	USE
Party	For listening in situations with many people talking at the same time
Social	Use this program if you are in small social gatherings, such as family dinners
Music	For listening to music

SPECIAL PROGRAMS	USE
Zen/Relax	Plays tones or noise for a relaxing sound background. For more information, see "The Zen program"
Phone	This program is designed for listening to phone conversations

SMARTTOGGLE PROGRAMS	USE
Zen+/Relax+	This program is similar to Zen but allows you to listen to different types of tones or noise using a remote control (RC-DEX or app)

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

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 using the latest Fractal technology. These sounds are shaped according to your hearing loss so you can listen to them at any time and at any place with a simple push of the program button. 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 light indicator signals

Ask your hearing care professional to turn the sound signals off if you do not need them.

Program sound signals

Your hearing aid plays sounds, SmartSpeak (spoken messages), to inform you which program you have activated or that you have changed program.

Program 1	Spoken message
Program 2	Spoken message
Program 3	Spoken message
Program 4	Spoken message
Program 5	Spoken message

Light indicator overview

Light indicators	Status
Five slow, green flashes 	The hearing aid is turning on
Six green flashes 	The hearing aid has successfully been paired with a Bluetooth device

Special care indication

This feature can be enabled by your hearing care professional

Light indicators	Status
Continuous green flashes 	The hearing aid is turned on Battery more than 20%

Light indicators

Continuous red flashes



Status

The hearing aid is turned on
Low battery, less than 20%



Lost partner

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.

Sound and program adjustment

MOMENT app

You can connect your smartphone to your MOMENT hearing aid with the MOMENT app to stream sound and control the functions of the hearing aid. For example, you can personalize your listening experience, change programs, and adjust or mute the sound in your hearing aid.

Remote control

If you have a remote control, you can also change program or 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.

Using a smartphone with your hearing aid



When you use a smartphone, hold it in front of you so that the microphone on the phone is close to your mouth. This way you will experience the best sound during your phone call.

PAIRING WITH YOUR SMARTPHONE

Connecting with your smartphone via Bluetooth

To pair your hearing aid and smartphone you need to restart your hearing aid. Do as follows:

1. Restart your hearing aid by placing it back in the charger and then removing it again.
2. Keep the hearing aid close to your phone and follow the instructions in the MOMENT app.
3. The hearing aid and smartphone are now ready for use.

NOTE

Your hearing aid is only in pairing mode for three minutes after you restart it. You might need to restart it again if you do not pair it in time.

How to connect the hearing aid to the app

When you have paired your hearing aid with your smartphone (in the settings menu), open the MOMENT app and it automatically connects to the hearing aid.

How to turn off the Bluetooth connection

Go to the More menu in the MOMENT app and select “Hearing aid Bluetooth” to turn off the Bluetooth connection. Bluetooth will reconnect once the hearing aid has been restarted.

You can see a list of compatible smartphones, tablets, etc. at this website:
www.widex.com/support/compatibility/

CLEANING

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



Wipe the hearing aid off with a soft, dry cloth.
If the microphone openings are blocked, contact your hearing care professional.

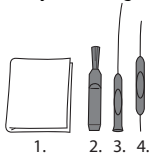
If you notice any dust or dirt in the microphones, gently blow it away or wipe it off with a soft cloth.

Dry your hearing aid quickly if it gets wet, or if you perspire heavily.

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

Tools

With your hearing aid, you will receive the following cleaning tools:



1. Cloth
2. Brush for ear-set
3. Long wax-removing tool for ear-set
4. Short wax-removing tool for ear-set

Wax guard

The wax guard is a filter placed in the opening of the receiver behind the ear-tip, and it helps to protect the receiver against earwax. Always use wax guards supplied by Widex with your hearing aid.

For information on how to change the wax guard, see the ear-set manual.

ACCESSORIES

You can use a variety of accessories with your hearing aid. Ask your hearing care professional if you could benefit from using these accessories.

Name	Use
RC-DEX	remote control
TV-DEX	for listening to TV and audio
PHONE-DEX 2*	for easy landline use
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
TV PLAY	for direct TV streaming
WPP401	standard charger for the MRRLD hearing aid
MOMENT APP	for using your smartphone to control your hearing aids
Sound Assist	for transmission of audio signals from the built-in microphones to the hearing aids
SoundConnect	dongle for streaming from PC to your hearing aids

* 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	Turn the hearing aid on by placing the hearing aid in the charger for 10 sec., and taking it out
	The hearing aid is not charged	Charge the hearing aid in the charger
The hearing aid is completely silent although charged and turned on	The wax guard is blocked with ear wax.	Remove the ear-tip from the earwire/tube. If ear wax has accumulated in the wax guard, change the wax guard. For further information, see the ear-set manual. You can also contact your hearing care professional for advice
The hearing aid volume is not powerful enough	Your ear is blocked by earwax	Contact your doctor

Problem	Possible cause	Solution
	The wax guard is blocked with ear wax.	Remove the ear-tip from the earwire/tube. If ear wax has accumulated in the wax guard, change the wax guard. For further information, see the ear-set manual. You can also contact your hearing care professional for advice
	Your hearing may have changed	Contact your hearing care professional/Contact your doctor
The hearing aid whistles continuously	Your ear is blocked by earwax	Contact your doctor
	The ear-set is not placed correctly	See "Putting on and removing the hearing aid"
Your two hearing aids are not working in synchrony	The connection between the hearing aids is lost	Turn them off and on again
The two hearing aids do not respond with a corresponding change in volume or program to the accessory	The accessory is used beyond the transmission range	Move the accessory closer to the hearing aids

Problem	Possible cause	Solution
	Strong electromagnetic interference	Move away from known source of electromagnetic interference
	The accessory and the hearing aids are not matched	Check with your hearing care professional to make sure the accessory is matched with the hearing aids

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.

TRAVELLING ON AN AIRPLANE

The hearing aid and the charger are allowed in both hand luggage and checked luggage.

You need to turn off the Bluetooth connection on the hearing aid by using the app. There is no risk of transmitting from the hearing aid's 2.4 GHz radio transmitter as long as the hearing aid is not connected to the mobile phone.

REGULATORY INFORMATION

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.

Wireless radio transmission

Wireless functions and operating characteristics

The following tables summarizes the technical details of the wireless technology:

Technical details	Inductive radio	Bluetooth LE
Antenna type	Integral coil antenna	Integral frame antenna
Antenna dimensions	Ø 2 mm, L 5 mm	18 mm x 4.5 mm
Modulation	FSK	GFSK / FHSS
Magnetic field strength	-30 dBµA/m @ 10 m	-
Output power (EIRP)	-	0 dBm / 1 mW
Range	0.3 m	6 m

Technical details	Inductive radio	Bluetooth LE
Center frequency	10.6 MHz	2401 MHz – 2480 MHz
Channel	Single Channel	40
Bandwidth	660 kHz	2 MHz
Data rate	212 kbps	1 Mbps
Data flow	Simplex/Semi duplex	Duplex
Protocol	Random Access / Pro- prietary	BLE

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.

Electromagnetic emissions/immunity standards

The product complies with the following EMC/EMI standards:

Standard	Test type	Note
47 CFR Part 15, Subpart B	RF emissions	US FCC requirements for unintentional radiators
47 CFR Part 15, Subpart C	RF emissions	US FCC requirements for intentional radiators
IEC 60601-1-2	General EMC including RF emissions, RF immunity, ESD	Medical Electrical Equipment, Electromagnetic compatibility
IEC 60118-13	RF immunity	International standard for hearing instruments to ensure adequate immunity radio interference from mobile telephones

EU directives

Directive 2014/53/EU

WSAUD A/S hereby declares that this MRRLD is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. The MRRLD contains radio transmitters operating at: 10.6 MHz, -54 dB μ A/m @10 m, 2.4 GHz, 0.9 mW EIRP.

A copy of the Declaration of Conformity according to 2014/53/EU can be found at:

www.widex.com/doc

To avoid potential degradation of radio performance, your device should be separated by at least 25 cm (10 inches) from other radio communications equipment.



Information regarding disposal

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

Hearing aids, hearing aid accessories and charger should be disposed of at sites intended for electrical waste and electronic equipment, or given to your hearing care professional for safe disposal.

FCC and ISED statements

FCC ID: 2AXDT-RFM014

IC: 26428-RFM014

HVIN: RFM014

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:

- 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 WSAUD A/S could void the user's authority to operate the equipment.

ISED Statement / Déclaration d'ISED

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

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

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique 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;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

ISED RADIATION EXPOSURE STATEMENT:

This equipment complies with ISED RF 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.

ISED EXPOSITION AUX RADIATIONS:

Cet équipement est conforme avec ISED les limites d'exposition aux rayonnements définies pour un contrôlé environnement. Cet émetteur ne doit pas être co-localisés ou fonctionner en conjonction avec une autre antenne ou émetteur.

SYMBOLS

Symbols commonly used by WIDEX in medical device labelling (labels/IFU/etc.)

Symbol	Title/Description
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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.



Catalogue number

The product's catalogue (item) number.
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Consult instructions for use

The user instructions contain important cautionary information (warnings/precautions) and must be read before using the product.
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Warning

Text marked with a warning symbol must be read before using the product.
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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 mark

The product is in conformity with the requirements set out in European CE marking directives.

Symbol	Title/Description
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	RCM mark
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	The product complies with electrical safety, EMC and radio spectrum regulatory requirements for products supplied to the Australian or New Zealand markets.
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	Medical device
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	Indication that the device is a medical device.
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WSAUD A/S

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