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Phonak PilotOne II

User Guide



PHONAK
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1. Welcome

Your new PilotOne II is a quality product developed by Phonak, one of the world's leading companies in hearing technology.

Read the user instructions thoroughly in order to benefit from all the possibilities your hearing system offers.

For further questions, please consult your hearing care professional.

 **Compatibility information:**
Check your hearing aid compatibility with your hearing care professional.

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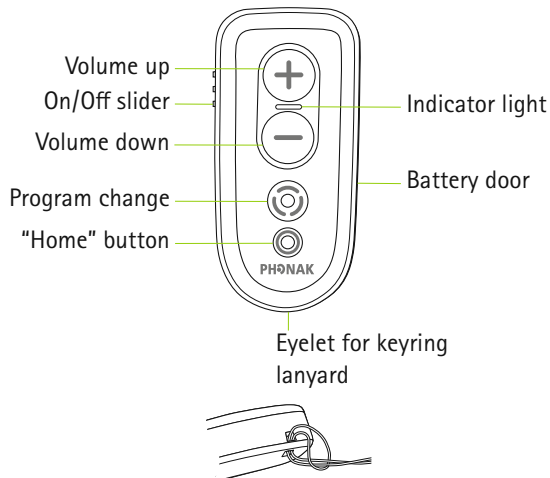
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CE mark applied: 2020

2. Description

The intended use of the PilotOne II remote control is to enable easy changes of your hearing aid programs and volume.

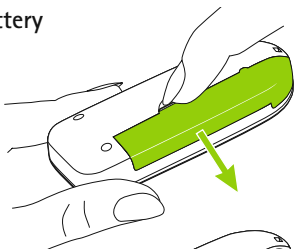


 The PilotOne II must be configured for your hearing aids by your hearing care professional before you can use it.

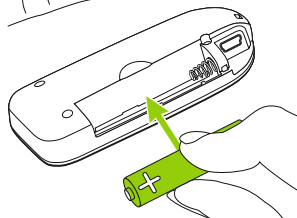
3. Using Phonak PilotOne II

3.1 Inserting a new battery

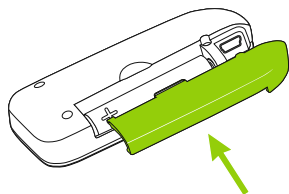
Slide battery cover in direction of the arrow to remove it.



Insert new battery with correct +/- position (Alkaline 1.5 V, type AAA, LR03 or AM4).



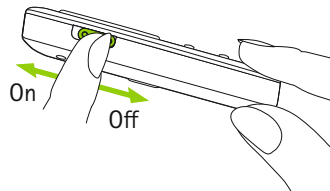
Secure battery cover by sliding it back into place.



i The mini-USB port cannot be used for battery charging. Do not use rechargeable batteries.

3.2 Switching On/Off

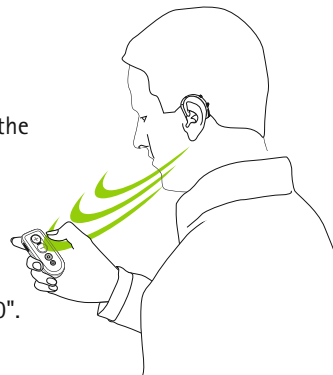
Use the slider to switch on or off.



3.3 Holding PilotOne II

Hold PilotOne II so that the buttons are facing you.

Maximum operating distance between the hearing aids and PilotOne II is 1 meter / 40".





3. Using Phonak PilotOne II

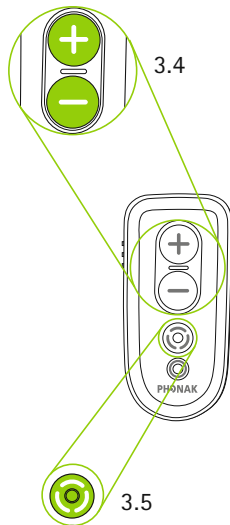
3.4 Changing hearing aid volume

Press "+" to increase volume

Press "-" to decrease volume

If configured by your hearing care professional

- Press and hold the volume down  button (2 sec) to mute your hearing aids.
- Press and hold the volume up  button (2 sec) to unmute again.

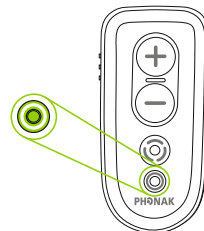


3.5 Changing hearing program




Each press of the program button will switch your hearing aids to the next available program.

3.6 Using the "Home" button

Press the "Home" button to return to the startup hearing program and default volume levels of your hearing aids.



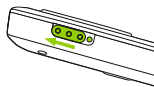
Press and hold the home button (>2 sec) to activate your main hearing program as configured by the hearing care professional.

-  Hearing aids will beep to confirm chosen selection.
-  Changes are applied to both hearing aids at the same time.
-  For information about your personal settings, ask your hearing care professional to print your PilotOne II instructions.

3. Using Phonak PilotOne II

3.7 Understanding the indicator light

When switching PilotOne II on, the indicator will switch on for two seconds indicating that PilotOne II is ready to use.




The indicator light remains on as long as a button is pressed.

i If the indicator does not blink when a button is pressed, PilotOne II needs to be programmed first by the hearing care professional.

The indicator light will be either green or red depending on the battery status.



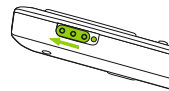
 Green: Battery ok

 Red: <10% left. Replace the battery immediately

4. Troubleshooting

No indicator light when a button is pressed:

- Switch on PilotOne II



i If the indicator light still does not blink while switching on, replace the battery (see chapter 3.1).

Hearing aids do not respond to the PilotOne II commands:

- Make sure your hearing aids are switched on and worn correctly
- Make sure PilotOne II is switched on
- Hold the PilotOne II closer to your hearing aids
- If indicator light does not blink or blinks red while pressing a button, replace the battery

i If your hearing aids still do not respond, ask your hearing care professional to re-program your PilotOne II.

5. Compliance information

Declaration of conformity

Hereby Phonak AG declares that this Phonak product is in compliance with the essential requirements of the Medical Device Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The full text of the EU Declaration of Conformity can be obtained from the manufacturer or the local Phonak representative whose address can be taken from the list on <https://www.phonak.com/com/en/certificates.html> (Phonak worldwide locations).

Australia/New Zealand:



R-NZ

Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.

The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1.

FCC ID: KWC-PILOTONE2
IC ID: 2262A-PILOTONE2

Notice 1:

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. 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.

Notice 2:

Changes or modifications made to this PilotOne II not expressly approved by Phonak may void the FCC authorization to operate this device.

Notice 3:

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

5. Compliance information

This device 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 device 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 device and receiver.
- Connect the device 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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident

that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat.

To report an unexpected operation or event, please contact the manufacturer or a representative.

Diligent and routine care of your PilotOne II contributes to outstanding performance and a long service life. To ensure a long service life, Phonak AG provides a minimum of a five year service period after phase out of the respective product.

For more information regarding features, benefits, setup, use and maintenance or repairs of your accessories – contact your hearing care professional or manufacturer representative.

Additional information can be found in the Data Sheet of your product.

5. Compliance information

For any information regarding the repair service of the hearing aid accessories please contact the hearing care professional.

Intended use: The intended use of the remote control is to enable changes of the hearing aid programs and volume.

Indication: Presence of hearing loss and hearing aids with individual fitting, compatible with Pilot One II

Contra-Indication: none

Target population: Target group are people with hearing loss wearing compatible Phonak hearing aids. No restrictions on the hearing loss level.

PilotOne II is suitable for the home healthcare environment and due to their portability it may happen that it is used in professional healthcare facility environment like physician offices, dental offices etc.

Emission standards:

EN 60601-1-2:2015, IEC 60601-1-2:2014,
EN 55011:2009+A1, CISPR11:2009/AMD1:2010,
CISPR22:1997, CISPR32:2012, ISO 7637-2:2011,
CISPR25:2016, EN 55025:2017

Immunity standards:

EN 60601-1-2:2015, IEC 60601-1-2:2014,
EN 61000-4-2:2009, IEC 61000-4-2:2008,
EN 61000-4-3:2006+A1+A2,
IEC 61000-4-3:2006+A1+A2, EN 61000-4-4:2012,
IEC 61000-4-4:2012, EN 61000-4-5:2014,
IEC 61000-4-5:2014, EN 61000-4-6:2014,
IEC 61000-4-6:2013, EN 61000-4-8:2010,
IEC 61000-4-8:2009, EN 61000-4-11:2004,
IEC 61000-4-11:2004, IEC 60601-1 (§ 4.10.2):2005,
ISO 7637-2:2011

Antenna:

Ferrite antenna

Type: integrated

Operation frequency: 10.6 MHz

Occupied bandwidth (99% BW): 534 kHz

Magnetic field strength @ 10 m: -14.5 dB μ A/m

Operating range to hearing aid: 100 cm (40")

6. Service and Warranty

6.1 Local warranty

Please ask the hearing care professional, where you purchased your device, about the terms of the local warranty.

6.2 International warranty

Phonak offers a one year limited international warranty, valid as of the date of purchase. This limited warranty covers manufacturing and material defects. The warranty only comes into force if proof of purchase is shown. The international warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods.

6.3 Warranty limitation

This warranty does not cover damage from improper handling or care, exposure to chemicals, immersion in water or undue stress. Damage caused by third parties or non-authorized service centers renders the warranty null and void.

Serial number:

Date of purchase:

Authorized hearing care professional (stamp/signature):

7. Information and explanation of symbols



With the CE symbol, Phonak AG confirms that this Phonak product meets the requirements of the Medical Device Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives.



This symbol indicates that the products described in these user instructions adhere to the requirements for an applied part of Type B of EN 60601-1. The surface of the device is specified as an applied part of Type B.



This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.



Indicates the medical device manufacturer, as defined in Medical Device Regulation (EU) 2017/745.



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides.



Important information for handling and product safety.



The device is a medical device.



Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union.

7. Information and explanation of symbols



Temperature transport and storage:
-20° to +60° Celsius
(-4° to +140° Fahrenheit).
Temperature operation:
0° to +40° Celsius
(+32° to +104° Fahrenheit).



Keep dry



Humidity transportation and storage:
up to 90% (non condensing).
Humidity operation:
<95% (non condensing).



Atmospheric pressure:
Transportation, storage and operation:
500 hPA to 1060 hPA.



The symbol with the crossed-out garbage bin is to make you aware that this device may not be thrown away as normal household waste. Please dispose of old or unused device, at waste disposal sites intended for electronic waste, or give your device to your hearing care professional for disposal. Proper disposal protects the environment and health.

8. Important safety information

Please read the information on the following pages before using your device.

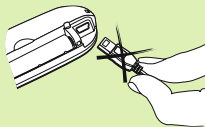
1. Hazard warnings

- ⚠ Keep this device out of reach of children aged under 3 years and mentally challenged people or pets.
- ⚠ This remote control uses low-power, digitally coded transmission to communicate to your hearing system. Although unlikely, interference with medical devices (i.e. pacemakers, defibrillators, etc.) is possible. Therefore users must not keep this remote control in or near a breast pocket.
- ⚠ Only use hearing aids that have been specifically programmed for you by your hearing care professional.
- ⚠ Changes or modifications to the device that were not explicitly approved by Phonak are not permitted. Only use accessories approved by Phonak to avoid any electrical shock.

- ⚠ Batteries are toxic. Do not swallow them! Keep out of reach of children and mentally challenged people or pets. If batteries are swallowed, consult your physician immediately!
- ⚠ Remove the battery if you are not using PilotOne II for a long period of time.
- ⚠ Always use a high quality, long-life alkaline battery as a replacement and dispose of the old one in an environmentally-friendly way. Do not use rechargeable batteries.
- ⚠ External devices may only be connected if they have been tested in accordance with corresponding IEC standards.
- ⚠ Using the device, its connectors or cables in any way contradictory to their intended purpose as described in this user guide (e.g., wearing the USB cable around the neck) can cause injury.

8. Important safety information

⚠ The mini-USBport is to be used for programming purpose only by your hearing care professional.



⚠ Do not use the device in explosive areas (flammable anesthetics, mines or industrial areas with a danger of explosions), oxygen rich environments or where electronic equipment is prohibited.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external an-

tennas) should be used no closer than 30 cm (12 inches) to any part of the Pilot One II including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2. Information on product safety

- ① Protect the device from excessive moisture (bathing, swimming), heat (radiator, car dashboard) or direct skin contact when sweating (workout, fitness, sport).
- ① Do not drop the device. Dropping onto a hard surface can damage your device.
- ① Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your device. Remove and keep it outside the examination room/area before undergoing:
 - Medical or dental examination with X-ray (also CT scan).
 - Medical examinations with MRI/NMRI scans, generating magnetic fields.

8. Important safety information

- ① Protect the PilotOne II sockets and battery slot from dirt and debris.
- ① Do not use your PilotOne II in areas where electronic equipment is prohibited.
- ① The digitally-coded, inductive transmission technology used in the device is highly reliable and experiences virtually no interference from other devices. It should be noted, however, that when operating the hearing system near computer equipment, larger electronic installations or other strong electromagnetic fields, it may be necessary to be at least 60 cm (24") away from the interfering device to ensure proper operation.
- ① Keep the device at least 10 cm away from any kind of magnets.
- ① When the device is not in use, turn it off and store it safely.

3. Other important information

- ① High-powered electronic equipment, larger electronic installations and metallic structures may impair and significantly reduce the operating range.
- ① If the hearing aids do not respond to the device because of an unusual field disturbance, move away from the disturbing field.

