

Ingenia by Phonak Acoustic

Implants

User Guide



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1 WELCOME:

Your new Ingenia is a premium Swiss quality product. It was developed by Phonak Acoustic Implant, combining the know how of Phonak, the leading provider of hearing system, the precision mechanics skills borrowed from the Swiss watch industry and the medical expertise from several renown research centres and universities.

This engineering marvel is easy to use. Many automatic functions offer maximum sound quality, the highest speech clarity, and optimal hearing comfort in almost all hearing situations. We are convinced that the outstanding performance of your Ingenia will provide valuable benefits to your daily life.

Please read these instructions thoroughly in order to benefit from all the possibilities your new hearing system has to offer. With proper use and care, you will be able to enjoy your hearing system for many years to come.

If you have any questions, please consult your hearing care professional.

www.acousticimplants.com



2 IMPORTANT INFORMATION

Please read the information on the following page before using your Ingenia

2.1 Patient card

Carry your Ingenia patient card with you at all times. If you need medical assistance, show this card to the treating health care professional.

2.2 Hazard warnings



Do not share your Ingenia speech processor with other people who have a middle ear implant. The processor is programmed specifically for your needs. Another person's processor may cause damage to your own hearing.




Avoid strong jolts and vibrations. You can play non contact sports if you have secured the Button Processor and protected it from physical damage. If there is risk of a blow to the head, it is advisable to remove the Button Processor and wearing some head protection. Contact sports should be avoided where physical injuries, pressure and blows to the head are possible. If head protection or goggles are worn, take care that pressure is not placed on the receiver coil that is implanted under your skin.





Care must be taken to avoid electric shocks, which could damage the DACS PI implant even if the Button Processor has been removed. You should be aware of static electricity, which could affect the performance of your Button Processor. Avoid touching computer or television screens. When getting out of a car, keep hold of the car until your feet touch the ground.





It is possible that the DACS PI implant and Button Processor could set off a shop security system or could activate the alarm when passing through an x-ray security machine (e.g. airport, some security controlled buildings). Always carry your DACS PI implant card for these situations. It is advisable to switch off the Button Processor when passing through an x-ray security control.

 You should switch off the Button Processor when taking off and landing during air travel; as with the cell phones and laptops


 Do not work in areas with strong magnetic fields (strong electromagnets) and do not use induction appliances (e.g. induction cooker) as these also have strong magnetic fields that could interfere with your implant.


 Sound quality may be distorted when you are near a radio or television transmission tower. It may also be distorted with a mobile phone. The effect is temporary and will not damage your system.


 Never swallow the battery. Always keep the battery out of the reach of young children to prevent it from being swallowed. If it is swallowed, consult a physician immediately.


 Do not fiddle with your implant (through the skin). Use precaution when scratching , rubbing etc. the region of the implant.

2.3 Information on product safety

 Remove the Button Processor when showering, bathing or swimming, as it is not waterproof. The Button Processor is splash proof for a short time; however you should avoid getting it wet. If you drop it in water, you can clean it, dry it and reuse it. If it is not working correctly after being in water, contact your audiologist.

 Sports at extreme pressures should be avoided e.g. deep sea diving and high altitude climbing, as the pressure could affect your DACS PI implant.

 Protect Button Processor from excessive heat. Do not leave the Button Processor near windows or in a car.

 At this time, MRI (magnetic resonance imaging) scans and therapeutic levels of ultrasound are contraindicated. You should consult with your DACS PI surgeon before undergoing any medical or cosmetic treatment using electricity or any diagnostic test involving x-ray or ultrasound. Always remove the

Button Processor if you are going to have an X-ray
or CT scan.

3 DESCRIPTION

The Button Processor is made of plastic and has a rounded, smooth shape to cause as little irritation to your skin as possible. The main controls on the Button Processor can be viewed in figure 1 below.

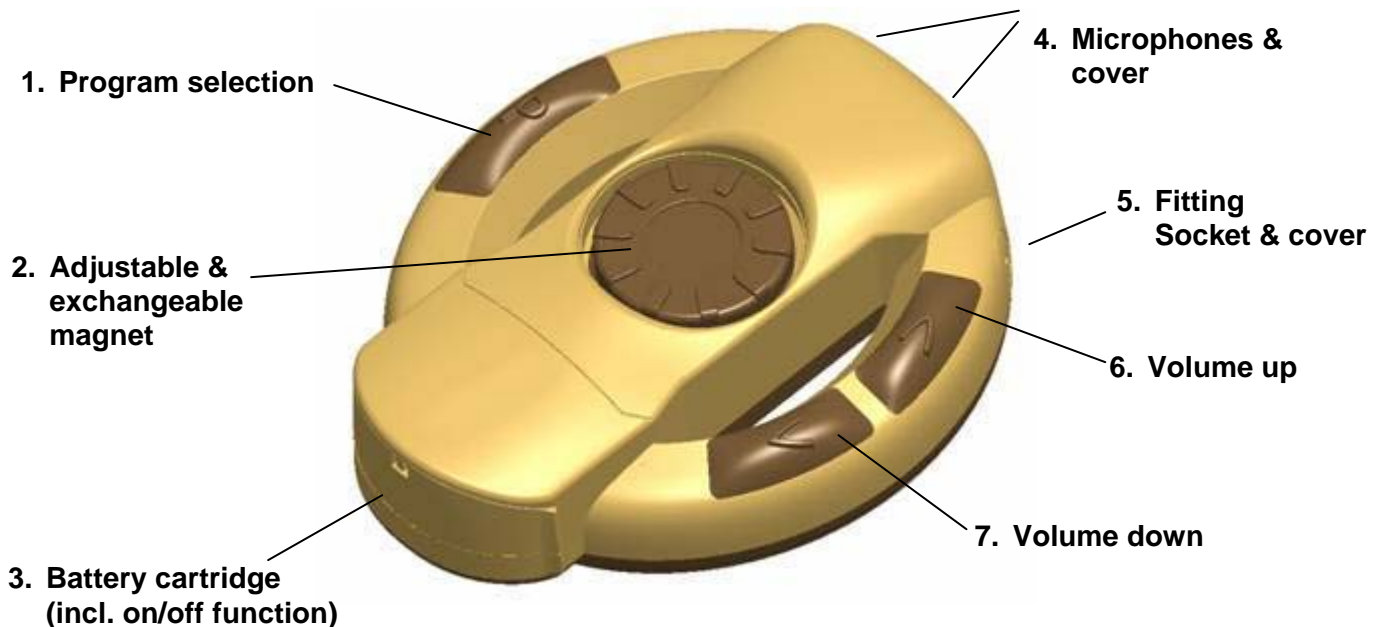


Figure 1: Button Processor Control Elements

Key

1. Program selection - allows choice of up to 3 different programs after fitting has been done
2. Adjustable & exchangeable magnet - allows different strength magnet to be used to adjust attachment to head.
3. Battery cartridge - holds battery. If cartridge opened, Button Processor is switched off.
4. Microphones and cover - microphones detect sound and cover protects microphones from dust.
5. Fitting Socket & cover - allows audiologist to connect the Button Processor to fitting software via the programming cable to adjust programming. Cover protects the fitting socket.
6. Volume up control.
7. Volume down control.

4 STEP BY STEP INSTRUCTIONS FOR USING INGENIA

4.1 Positioning of the Button Processor

During your operation, a receiver coil has been implanted below your skin. It allows the Button Processor to "communicate" with the DACS PI implant. Both the receiver coil and the Button Processor have magnets. The adjustable magnet in the Button Processor will help you to place it automatically correctly over the receiver coil, so that you get the best effect from your implanted DACS PI device.



Figure 2: Button Processor location on the head

The orientation of the Button Processor can easily be changed in order to get the microphones into the best position. The magnet in the Button Processor allows you to place it correctly on your head but doesn't stop you from adjusting the orientation of the Button Processor. You can rotate the Button Processor, so that the battery compartment is facing downwards and the microphones are in the upward position (best position). The Button Processor will easily rotate when you move it as there is very little friction with your skin and hair. However, the Button Processor has little points underneath it to stop it moving by itself, so that it does not slip while you are going through your daily activities (see figure 3).



Figure 3: View of the Button Processor contact surface against skin

The Button Processor magnet sits in a little recess, so that only the outer ring of the Button Processor is in contact with your skin. This reduces the pressure on your skin, when the Button Processor is attached and so avoids skin irritation.

Magnets with different strengths are available. Your audiologist can help you select the one(s) that is/are best for you.

4.2 Removal of the Button Processor

By pulling on the Button Processor with a gentle force, it can be removed.

4.3 Battery Replacement

The battery (675 ZnAir Battery) is located in a removable battery cartridge. It will last approximately one day with normal use. The Button Processor will beep 6 times when the battery is low, to let you know that it will need changing. To exchange the battery, hold the 2 grips at the side of the battery cartridge with your thumb and index finger and pull it out. The battery cartridge has to be removed completely from the Button Processor casing to allow a good access to the battery (see figure 4).

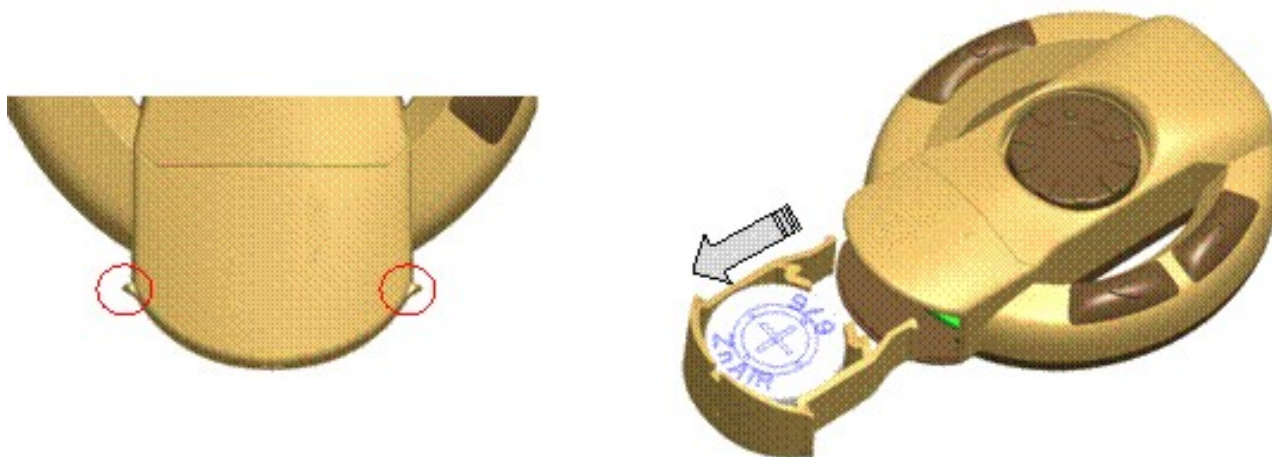


Figure 4: Remove the cartridge completely for battery replacement

The battery itself is not firmly fixed into the battery cartridge so that you can easily remove it. The cartridge has a small '+' inscription on the top surface, as well as a diagram on the side, to show you which way up to insert the new battery. In addition, the cartridge has a recess in it, which stops the battery being inserted in the wrong way (see figures 5 and 6).

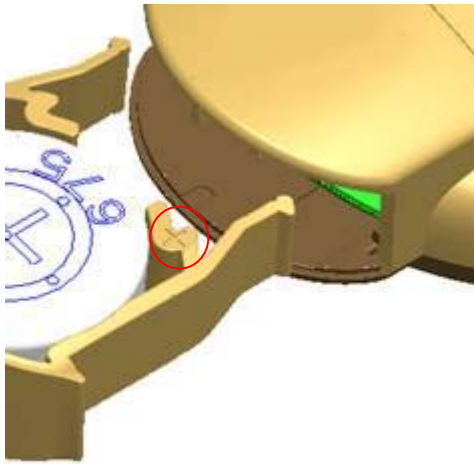


Figure 5: Correct orientation of the battery is indicated on the cartridge

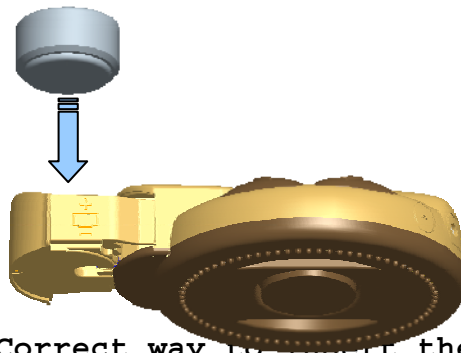


Figure 6: Correct way to insert the battery

A battery may sometimes present evidences of leakage. Do not use such batteries. If the leakage occurred while the battery was inserted in the processor, contact your audiologist for replacement.

Hints:

- Always use new batteries as replacements. Do not insert used batteries into the Button Processor.
- Batteries should not be thrown away as household waste.
- If there is resistance when closing the battery compartment, check that the correct battery has been used and that it has been correctly inserted.
- Never swallow the battery. Always keep the battery out of the reach of young children to prevent it from being swallowed. If it is swallowed, consult a physician immediately.
- Only use ZnAir 675 batteries. NEVER use any other kind of battery as they may destroy the Button Processor.
- Never put batteries in the sun or heat them.
- Never put the switched on Button Processor on a metal surface as this will destroy the battery quickly.
- Always remove the protection label from the new ZnAir battery before inserting it into the Button Processor.

4.4 Switching On / Off

To switch off the Button Processor, pull out the battery cartridge by a few millimeters, in the same way that you would open the cartridge to change the battery (see figure 7). To turn on the Button Processor, pull on the battery cartridge. Do not wear the Button Processor while it is switched off.



Figure 7: Switch off position of the cartridge

Hint:

- Always switch off the Button Processor when not in use.

4.5 Change of Program

A different program can be selected by pressing on the **Program selection** push button (see figure 8). Your audiologist can set up to a maximum of 3 different programs in your Button Processor so that you can use it in different environments. There is also a mute program available if you wish to have this. The mute program can be used for example if the Button Processor is momentarily used in an environment causing interferences. Each time you change the program, the Button Processor will indicate this with a beep.

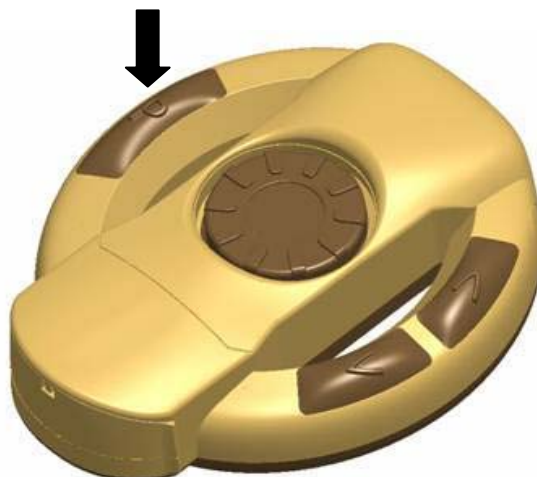


Figure 8: Program selection

Hints:

- If your Button Processor malfunctions, it has an inbuilt safety system which will inactivate it. If this happens, contact your audiologist and take the malfunctioning Button Processor with you to the next visit.
- If the Button Processor is not working correctly, try replacing the battery. If this does not resolve the problem, contact your Audiologist to have the Button Processor repaired.

4.6 Volume Level Adjustment

The volume level can be controlled by pressing on the top push button (UP) or on the bottom push button (DOWN). The Button Processor has been pre-programmed so that you can adjust the volume level between predefined limits. When the volume reaches a limit, the Button Processor will beep twice to let you know that you have reached this limit.



Figure 9: Volume setting

Each time you change the program or switch the Button Processor off, the volume will automatically be reset to neutral. If you prefer to have the volume set for each program so that it does not change to neutral each time the program is changed, ask your Audiologist to arrange this at your next fitting session.

4.7 Adapt holding force of the Button Processor

You can change the strength of the magnet by screwing or unscrewing it into the Button Processor. The fine force adjustment is done by turning the magnet while holding it between the thumb and the index finger (see figure 10). Put your thumb underneath the magnet and your index finger on top of the magnet to move it. Seen from the top of the device, a clock wise rotation of the magnet increases the holding force while a counter clock wise rotation decreases it.

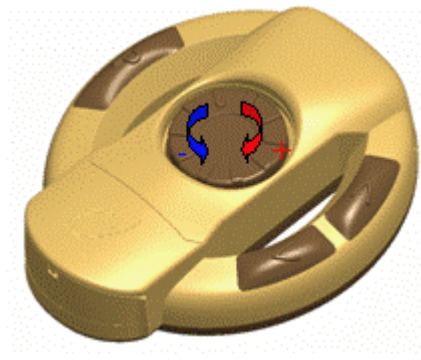


Figure 10: Fine adjustment of the holding force of the Button Processor

5 CARE AND MAINTENANCE

5.1 Fitting sessions

It is important to attend your scheduled fitting sessions with your audiologist for two reasons:

1. to ensure that the Button Processor does not supply too much energy to your ear, causing uncomfortable levels of sound.
2. to ensure that the Button Processor is programmed to give you the best possible level of hearing in your activities of daily living.

5.2 Cleaning of the button processor

Keep the Button Processor clean using surgical spirit or an alcohol based cleaning solution. Alcohol based wipes or refreshing tissues can also be used, as well as medicated wipes that are produced for hearing aids. Do not touch the microphones when cleaning the Button Processor. Do not use household cleaning products (e.g. washing powder, soap) to clean the Button Processor.

Remove the Button Processor before applying cosmetics as hair spray; face creams and make up can damage it.

Hint:

- Always remove the battery before cleaning the Button Processor. Never touch the battery with the cleaning agent.

5.3 Care of Skin around the Button Processor

If your skin becomes irritated or sensitive in the area where the Button Processor attaches to your head, try to adjust the magnet to see if a less strong attachment will ease the sensitivity but still maintain a good connection between the Button Processor and the induction coil implanted under your skin. Avoid tight fitting hats or place straps from head gear in an area away from the receiver coil and Button Processor. If you experience inflammation in the area of the Button Processor, contact your audiologist or surgeon.

6 TROUBLESHOOTING

Problem	Action
Button Processor loses microphone cover or fitting socket cover or magnet	Contact Audiologist for replacement covers or magnet
Button Processor does not stay attached on head	<ol style="list-style-type: none"> 1. Screw the magnet in deeper into the Button Processor to increase the strength when it attaches to the head. 2. See with your Audiologist
Battery cartridge is loose	Contact Audiologist for a replacement
Button Processor is lost	Contact Audiologist for a replacement
Poor sound or no sound with Button Processor	<ol style="list-style-type: none"> 1. Insert a new battery 2. Check that the battery cartridge is tightly closed 3. Check that the Button Processor looks clean and is not greasy over the area of the microphones - clean gently with surgical spirit or alcohol based cleaner 4. Check that the Button Processor is positioned with the microphones upwards (change to a stronger magnet if button microphones do not stay in upward position) 5. Contact Audiologist if none of the above improves the poor sound. If Button Processor has been immersed in water, inform Audiologist.
Damage to Button shell	Contact Audiologist for a replacement
Program and volume buttons do not work as expected	Contact Audiologist for a repair or replacement

7 SERVICE AND WARRANTY

Phonak Acoustic implant offers you a comprehensive warranty, valid starting from the date of purchase. Please ask your hearing care professional about the term of the warranty valid in the country of purchase. The warranty covers repair in case of processing and material errors.

No warranty claims will be considered if the hearing system shows normal wear and tear, improper handling or care, exposure to chemical, immersion in water or undue stress. In case of damage caused by third parties or un-authorized service, the warranty is null and void. This warranty does not cover services performed by a hearing care professional at his or her workplace.

Ingenia serial number

Purchase date

8 INFORMATION AND EXPLANATION OF SYMBOLS

Notice

This device is certified under:

Ingenia/DACS PI



FCC ID: X47 - DACSPI
IC: 8812°- DACSPI

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.

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

Symbols



With this symbol, Phonak Acoustic Implant confirms that this product meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Active Implanted Medical Devices 90/385/EEC. The numbers after the CE symbol correspond to the code of the certified institutions that were consulted under the above-mentioned directives.



This symbol indicates that the product described in this user guide adheres to the requirement for application of EN/IEC 60601-1 and EN 60601-1-2.



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



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



This symbol indicates important information for handling and product safety.

Operating conditions

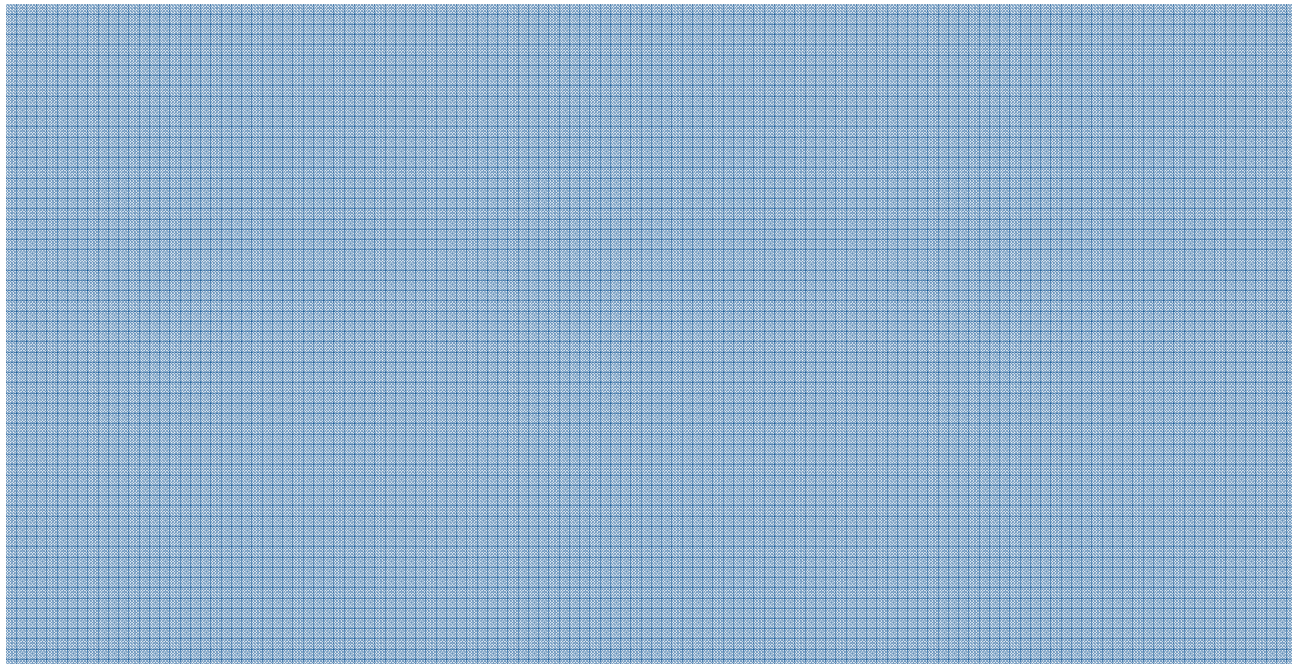
The product is designed such that its functions work without problems or restrictions if used as intended, unless otherwise noted in this user guide.

Transport and storage conditions

During transport or storage, the temperature should not exceed the limit values of -20°/60° Celsius and relative humidity of 65% for a long period of time. Air pressure range between 500 and 1100 hPa is appropriate.



This symbol makes you aware that this hearing system may not be thrown away as normal household waste. Please dispose of old or unused hearing systems at waste disposal sites intended for electronic waste, or give your hearing system to your hearing care professional for disposal. Proper disposal protects the environment and health.



Manufacturer

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Switzerland

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