

Distributor / Trust

LUMEN[®]
200B



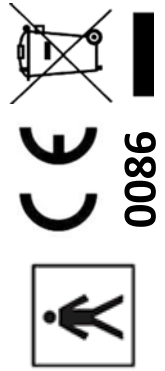
 IntriCon Corporation
1260 Red Fox Road
Arden Hills MN 55112 USA

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 CEpartner4U BV
Esdoornlaan 13, 3951DB Maarn,
The Netherlands

 Bluetooth[™]

QD ID: XXXXX

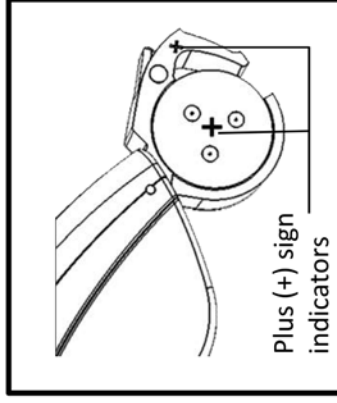


 IntriCon
The Body-Worn Device Company

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Quick Reference

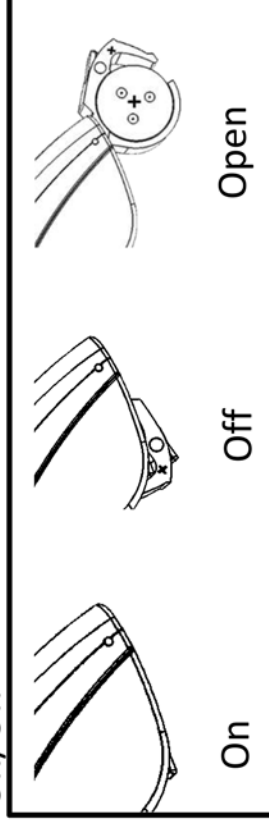
Changing Batteries



Battery Warnings



On/Off



Rocker Switch Operations

Press = Louder, Press and Hold = Change programs

Press = Softer, Press and Hold = Change programs

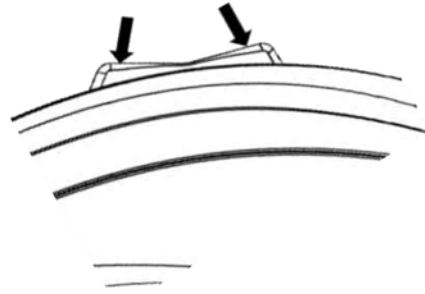
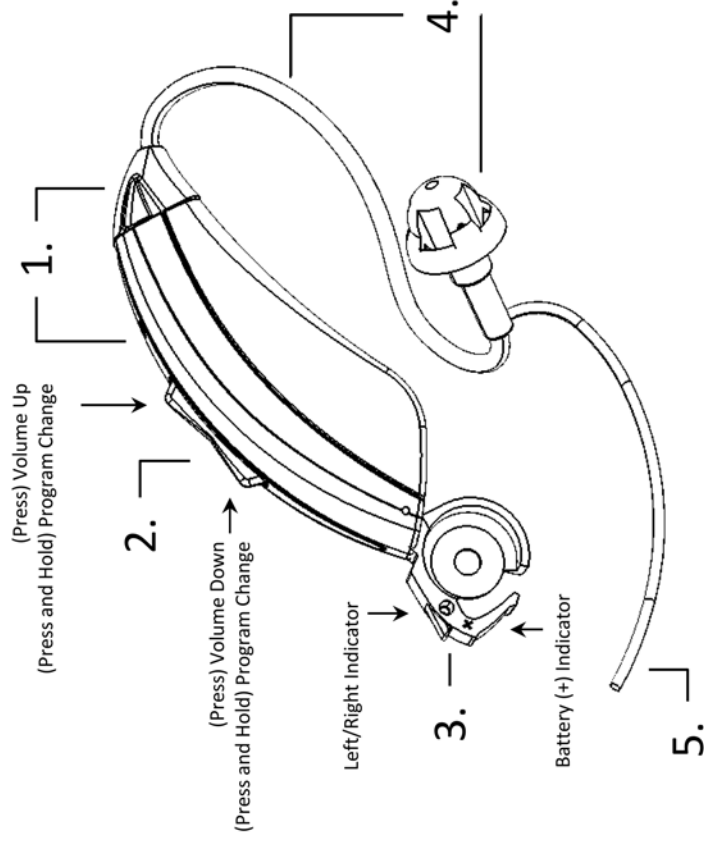


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Your Hearing Aids at a Glance

1. **Microphone and Receiver** – Sound enters the hearing aid through the microphone. The receiver delivers amplified sound through the tubing to the ear canal.
2. **Rocker switch** – A brief press is used to change volume up or down. Press and hold to change programs.
3. **Battery door** – The battery is inserted here and also functions as the on/off switch when operating the device. When the door is closed and battery inserted, the device will be on. Opening the door will turn off the hearing aids. A (+) indicator corresponds to the positive side of the battery. A small hole may be filled with a colored plug to be used as an optional indicator for the right or left ear.



Intended Use:

Hearing aids are sound-amplifying devices intended to compensate for impaired hearing. A hearing aid will not restore normal hearing, and will not prevent or improve biologic hearing sensitivity resulting from damage including but not limited to; the aging process, noise exposure, and/or head trauma.



For additional information on the use and operation of these hearing aids after reviewing the contents of this instruction guide, contact your hearing healthcare provider or visit www.intricon.com.

4. **Ear tube and Dome tip** – Each hearing aid comes with an ear tube and dome tip that connects to the hearing aid receiver. Sound travels through the tubing into your ear canal.
5. **Retention Loop** – Keeps the tubing securely in place on or over the ear.

Battery Information

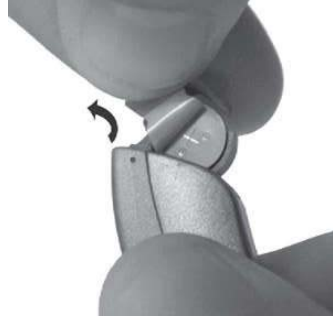
The hearing aid uses a size 312 battery. The battery life varies, depending on the amount of hearing aid use. Battery life is typically 7-10 days.

Low battery indicator

A warning of three double beeps every eight minutes indicates that the battery needs to be replaced. If you do not change your battery, you will hear another warning of six double beeps, at which time your hearing aid will automatically turn off.

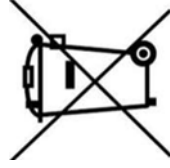
Inserting/replacing the battery

1. Gently pull open the battery door with your fingernail. If a used battery is currently in the compartment, grasp the battery with your thumb and index finger and remove.
2. Insert the new battery into the battery compartment with the (+) sign on the battery facing the same way as the (+) sign on the battery door. While holding the battery in place, peel off the plastic tab.



Battery warning information

Dispose of used batteries as you would other electronic waste that potentially contains rare earth metals. Do not place batteries in your mouth or swallow them under any circumstances.



If batteries are swallowed, contact your physician or local poison control center immediately.



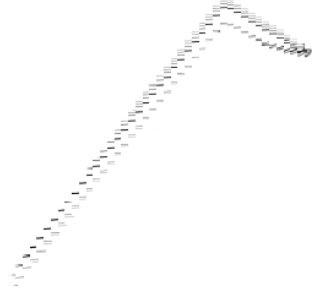
Note: Wait for a few seconds before closing the battery door after peeling the plastic tab. If the door does not close easily, check to see if the battery was inserted properly.

Note: To prolong battery life, remember to turn your hearing aids off when not in use. Remove the batteries and keep the battery door open will not only conserve the battery's life but also allow internal moisture to evaporate.

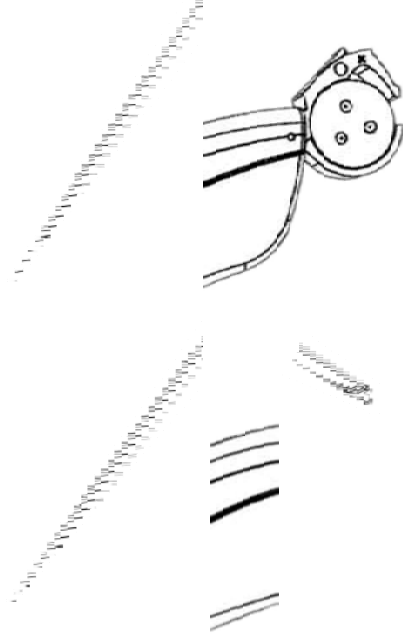
Turning your Hearing Aids On and Off

Your hearing aids have a battery door that acts as an off/off switch that allows access to the battery compartment.

1. ON: Close the battery door fully.



2. OFF: Open the battery door



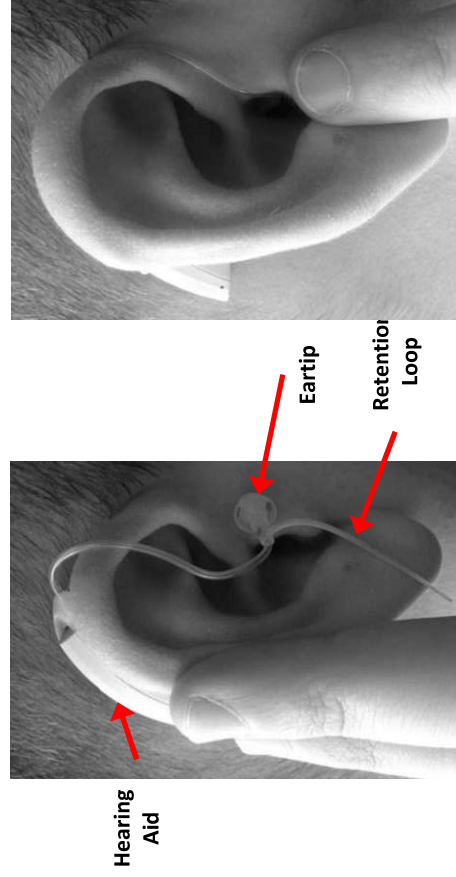
Note: It may take several seconds before the hearing aid turns on after inserting the battery. Your hearing healthcare provider can additionally increase the start up delay if required.

Note: When turning your hearing aid on and off, grasp the top and bottom of the device with your index finger and thumb. Use your thumb to open and close the battery door.

Wearing your Hearing Aids

1. Hold the ear mold or slim-tube between your thumb and index finger. The opening should be pointing in towards your ear canal with the hearing aid resting upwards over the top of your ear.
2. Place your hearing aid over the top of your ear until it rests securely over/behind the ear.
3. While holding the hearing aid in place, insert the ear tip into your ear canal, and curl/tuck the retention loop along the body of your ear.

Note: Pulling down and back on your earlobe may help you insert the slim-tube/ear mold into your ear canal more easily.



The ear tip should be completely or almost completely in the ear canal. Proper insertion of the ear tip is key to getting enough loudness and avoid whistling.

For hearing aids with ear molds, please consult with your hearing health professional about putting it on. If you wear eyeglasses, put your glasses on first and then put your hearing aid on.



Allergic reactions to hearing aids are unlikely. If you experience skin irritation, redness, or soreness in or around your ears, please contact your physician or hearing healthcare professional.

Operating Instructions

Note: For specific features and program settings tailored to your individual use patterns and settings of interest, speak to your hearing healthcare provider. They are trained to work with you to meet your communication needs.

Program control

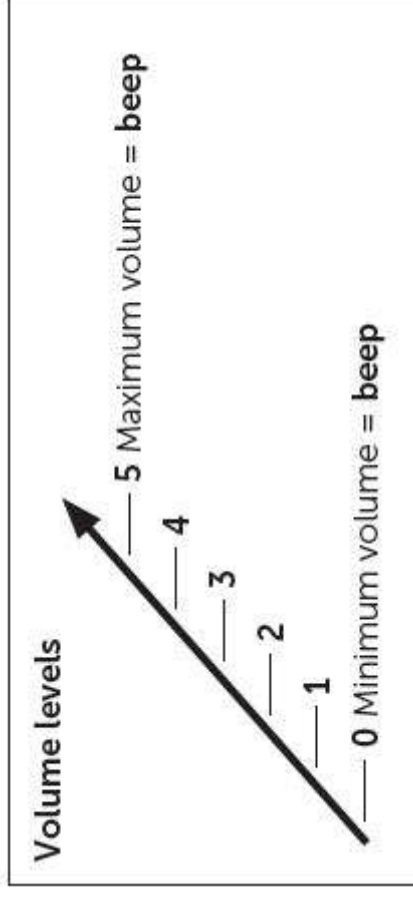
The rocker switch allows you to choose between several program settings. Press and hold until you hear a beep to change programs.

Use the program that sounds best the majority of the time. Within each program, you can also use the volume control to make sounds louder or softer. The hearing aid will beep to let you know which program has been selected. The dome tip or ear mold must be in your ear to hear the beep(s).

Program 1	♪	1 beep
Program 2	♪♪	2 beeps
Program 3	♪♪♪	3 beeps

Volume control

The rocker switch also allows you to choose between volume levels. Press and quickly release the top of the rocker switch to increase the volume. Press and quickly release the bottom of the rocker switch to decrease the volume. You will hear one beep when you reach the maximum or minimum volume setting.



Note: You should be able to wear your hearing aids at a comfortable volume without them whistling. If your hearing aid whistles, turn the volume down and/or contact your hearing healthcare provider.

Maintaining your hearing aids

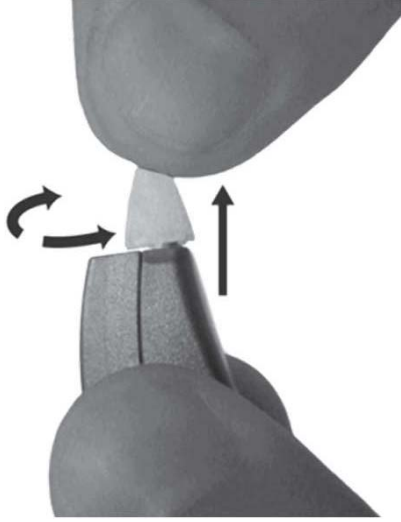
Depending on your hearing loss, your provider may have attached to a slim-tube and dome tip or a conventional ear mold.

Replacing slim-tube and dome tip:

Your ear tube and dome tip will come connected upon shipment. For optimal performance, replace ear tube and dome tip every three months.

Removing slim-tube and dome tip:

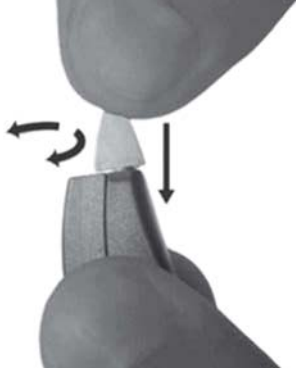
Grasp the “hearing aid end” of the slim tube; gently turn approximately 90 degrees and pull to remove the ear tube from the hearing aid.



Note: Do not bend the ear tube and tip back and forth to remove it.

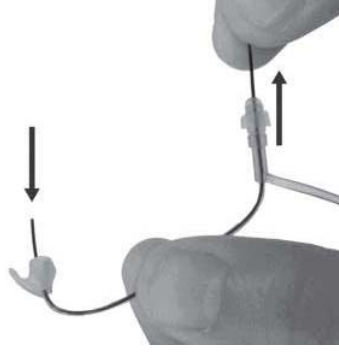
Attaching slim-tube and dome tip:

Gently push the “hearing aid end” of the ear tube onto the hearing aid until it snaps into position and rotate slightly to lock in place.



Cleaning slim-tube and dome tip:

Between replacements, you'll need to clean the slim-tube and dome tip with a cleaning wire to remove any debris or accumulated ear wax.



Do not use cleaning wire while the slim-tube is connected to the hearing aid or you may damage the hearing aid.



Maintaining your hearing aids

Detaching and cleaning ear molds

Note: Ask your hearing healthcare provider to see if this applies to you.

Ear wax is natural and common. Ensuring your hearing aids are free of wax obstruction is an important part of the daily cleaning and maintenance of your hearing aids.

- Remove the ear mold tube from the ear hook
- Wash the tube with warm soapy water, and blow air through the tube to remove any water left inside the tube
- Let the ear mold and tube dry overnight to allow any water left inside to dry
- After the ear mold and tube is dry, reconnect the ear mold tube to the ear hook



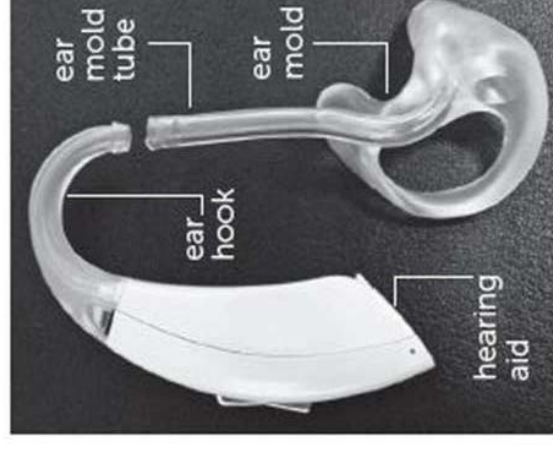
Do not use alcohol to clean your ear molds or dome tips.



Do not use sharp tools to dislodge ear wax.



If your physician prescribes eardrops, clean any moisture that may get into the ear molds or tubing.



Using Remote Control (optional)

Your Lumen 200B is compatible with Intricon's basic Remote Control unit (below).



The Remote Control allows you to control volume level and program number without using the hearing aid buttons.

If you have a remote control, this is how you connect your hearing aid to your remote control:

1. Turn L200B devices on by inserting batteries: Once the L200B's are on, place the devices on your ears. You should confirm operation of the devices by pressing the rocker switch to change the volume.
2. Insert batteries into the FOB: Insert 2x AAA batteries into the FOB.

4. Move the selector on the FOB to the device you want to pair: To pair your Right hearing aid to the FOB, move the selector to the right. To pair the left, move the selector to the left. If you have on hearing device, move the selector to the middle.

5. Press the pair button on the FOB: Behind the battery door is a small pair button. Press this to initiate the pair sequence. You will see the LED light up for the hearing device that is being paired.

NOTE: For optimal pairing performance, hold the FOB close to the device you are pairing.

6. Confirm successful pair: When pairing completes, the LED(s) will flash three times. Confirm the pairing is successful by pressing one of the FOB buttons and confirming functionality on the hearing aid, such as "Volume Up". If the FOB does not appear to be paired to the HA device, press the pair button again to repeat the pairing process.

Once the FOB is paired, the FOB will be functional with that hearing aid for the life of the product, or until a new Pair is established. This pair will be maintained throughout power cycles and battery replacements.

NOTE:

- If you do not have a remote control, please ask for one from your hearing care provider.
- Lumen 200B is also compatible with other Smart Bluetooth BLE[®] devices.

Caring for Hearing Aids

Open the battery door when not in use.

Protect your hearing aids from excessive heat.

Regular use of a dehumidifier can help prevent corrosion and prolong the life of your hearing aids.

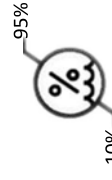
Always remove your hearing aids when using hair care products. The hearing aids can become clogged and cease to function properly.

Do not wear your hearing aids in the bath or shower or immerse them in water.

During transport or storage, the temperature should not exceed the limit values of 14° to 158° Fahrenheit (-10° to 70° Celsius) for a long period of time.

If your hearing aids do become wet, do not attempt to dry them in an oven or microwave. Do not adjust any controls. Open the battery doors immediately, and allow your hearing aids to dry naturally for 24 hours.

Do not drop your hearing aids or knock them against hard surfaces.

 During transport or storage, the relative humidity should not exceed the limit values of 10-95% for a long period of time.

 The air pressure range between 500 and 1100 hPa is appropriate

 In the event of unexpected operation or events, consult with your hearing healthcare provider or visit www.intricon.com for support.

Using with telephones and cellular phones

Traditional corded phones, cordless phones and cell phones

First, try to use the phone as you normally would hold it. If you cannot hear well, move the handset up slightly to find the position that sounds best to you. If you encounter whistling, tilt the phone handset at an angle until the whistling stops. It may help to turn the volume up on your phone. Practice using the telephone with someone familiar to you. Try moving the phone around to get the best sound.

Note: If your phone is labeled “Hearing Aid Compatible,” it works with a telecoil.

Telecoils

The Lumen 200B model contains a telecoil which converts electromagnetic signals directly from the telephone into sound. The telecoil setting turns off the regular microphone so you can hear more clearly on the telephone. After finishing your phone call, change back to your preferred program to turn on the hearing aid microphone again.

Other uses of a telecoil

Many people use the telecoil with assistive listening devices called induction loops. If you go to any events or religious services and the room is “looped” that means you can use your telecoil. Set your hearing aids to the telecoil program. When the speaker talks into the microphone, the sound will be picked up by the “loop.” The sound then goes into your hearing aid(s). It will turn off the background noise and allow you to hear the speaker more clearly. After the event, change back to your preferred program, to turn on the hearing aid microphone again.

Note: If you are in a location with an induction loop system, you will notice this symbol. This means the location you are presently in has special accommodations for the hearing impaired.



Troubleshooting Guide

CAUSE	POSSIBLE REMEDY
1. No sound or not loud enough	
Not turned on	Turn on by closing the battery door or clean wax out of tube
Low/dead battery	Replace battery
Ear wax	Clean/replace ear tube and dome tip
Battery upside down	Insert battery plus side (+) up
Moisture	Open battery door and allow to dry
2. Three double beeps	
Low battery	Replace battery
3. Whistling or feedback	
Dome tips not inserted properly	Remove and reinsert
Poor-fitting ear mold	Consult your hearing healthcare provider
Hair or clothing near ear	Remove hair or clothing near ear
Check for cracks in ear tube	Replace ear tube and tip
4. Poor fit	
Ear tip falling out of your ears	Contact your hearing healthcare provider
5. Wireless Issues	
Bluetooth connection failed	Unpair your hearing aids and turn Bluetooth off and on. Open and close battery door on hearing aids. Re-pair hearing aids.
Only one hearing aid paired	

Service and warranty

IntriCon offers you a comprehensive, worldwide warranty, valid starting from the date of purchase. Please ask your hearing healthcare provider about the term of the warranty valid in the country of purchase. The warranty covers repairs in case of processing and material errors.

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

Record the date purchased and other information about your hearing aids in the table below.

Left Hearing Aid	Right Hearing Aid
Date Purchased:	Date Purchased:
Place UDI label or record serial number here:	Place UDI label or record serial number here:



Warnings to Consumer

- Hearing aids should only be used as directed by your physician or hearing healthcare professional.
- Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- Do not use your hearing aids in explosion hazard areas.
- Allergic reactions to hearing aids are unlikely. However, if you experience itching, redness, soreness, inflammation or a burning sensation in or around your ears, inform your hearing healthcare professional and contact your physician.
- In the unlikely case that any parts remain in the ear canal after the removal of the hearing aid, contact a physician immediately.
- Remove your hearing aids for CT and MRI scans or for other electromagnetic procedures.
- It is possible to program Lumen 200B so it can produce sound pressure levels which exceed 132 dB SPL. This could cause further harm to your hearing. Speak with your hearing healthcare professional to ensure the maximum output of your hearing aids is suitable for your particular hearing loss.
- Never leave hearing aids or batteries where small children and pets can reach them. If batteries are swallowed, consult your physician or local poison control center immediately

- If you feel pain in or behind your ear, if it is inflamed, if skin irritation or accumulations of ear wax occur, please check with your hearing healthcare provider or physician
- Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e.g. cars, are partially or entirely suppressed



Use on Aircraft

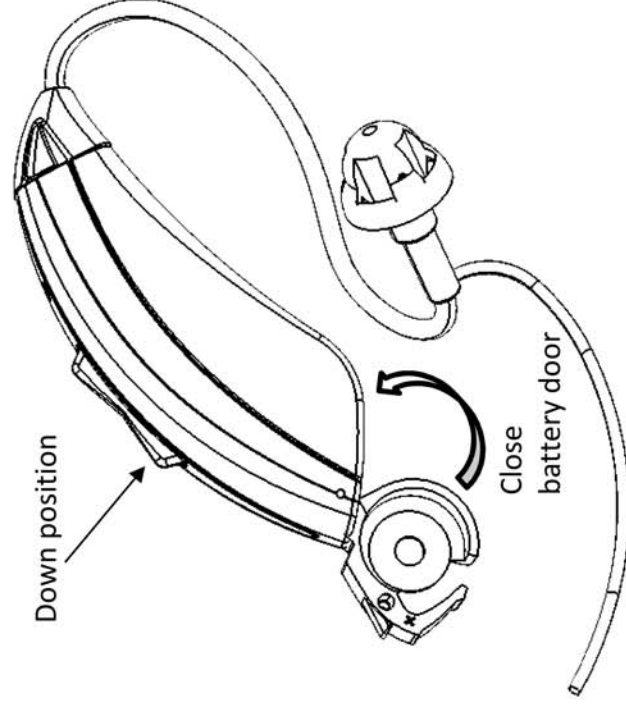
- Your hearing aid contains Bluetooth. On board an aircraft, flight mode must be activated, unless Bluetooth is permitted by the flight personnel.



Airplane Mode

When boarding a flight or entering an area where radiated radio signals are prohibited, wireless functionality must be deactivated; airplane mode must be turned on.

The airplane mode is enabled by closing the battery door whilst holding the rocker switch down position.

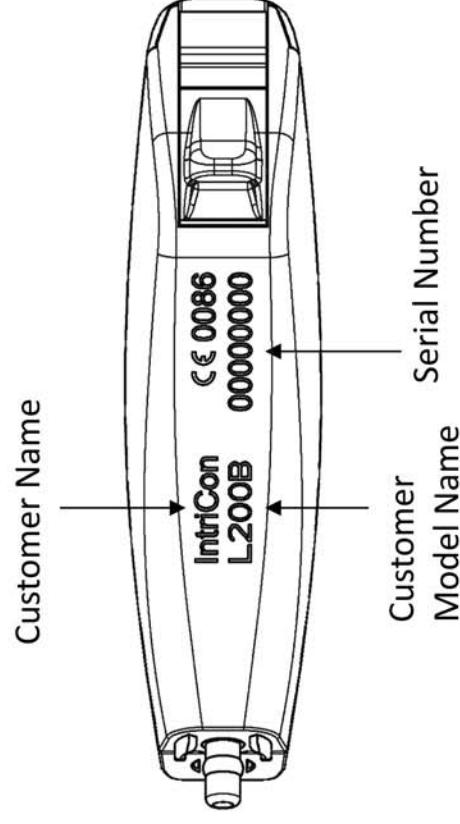


Labeling

The serial number (S/N) is located on the hearing aid as a 8-digit number. The first two digits of the S/N represent the year of manufacture (i.e. "15" refers to 2015). The last six digits is a unique identifier. All eight numbers create the serial number of the device.

Font = .04 ARIAL TEXT

Laser Mark Color: Black





Precautions

- The use of hearing aids is only part of hearing rehabilitation; auditory training, lip reading instruction, and learning to interpret gesture cues may be required as well.
- In most cases, infrequent use of hearing aids does not provide full benefit. Once you have become used to wearing your hearing aids, wear your hearing aids all day every day.
- Your hearing aids use the most modern components to provide the best possible sound quality in every listening situation. However, communication devices such as digital cell phones can create interference (a buzzing sound) in hearing aids. If you experience interference from a cell phone being used close by, you can minimize this interference in a number of ways. Switch your hearing aids to another program, turn you heard in a different direction or locate the cell phone and move away from it.

Warnings to Dispenser

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. [This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).]

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.

Compliance Information



With the CE symbol, Intricon confirms that this product – including accessories – meets the requirements of the Medical Device Directive 93/42/EEC as well as Radio Equipment Directive 2014/53/EU. A copy of the Declaration of Conformity can be obtained from Intricon. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives



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



Symbol for consult Instructions for Use.



Symbol for keep dry.



Symbol for caution. This is a safety symbol used to highlight that there are specific warnings or precautions associated with the devices that are not otherwise found on the label.



Telecoil compatible assisted listening Device



Intricon Corporation
1260 Red Fox Road
Arden Hills MN 55112 USA



Symbol for fragile, handle with care.



Year of manufacture is the first 2 digits of the serial number (assume 2 digits are preceded by "20"; e.g. "14" = year 2014)



Serial Number is located on part as a 8-digit number. Last 6 digits represent the serial number

FCC Information: **FCC ID: POMINHAB3A0**

Per FCC 15.19(a)(3) and (a)(4), this device complies with part 15 of the FCC Rules. Operation is subject to the following 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: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

Radio Equipment Directive Information:

The equipment operates in the ISM 2.4 GHz band (2.40 – 2.4835 GHz), using the Bluetooth™ SMART protocol, and the maximum RF Power transmitted in that band is -10.1 dBm EIRP.