

USER MANUAL
Novidan, Inc.
NoviOne RIC
Wireless

DRAFT



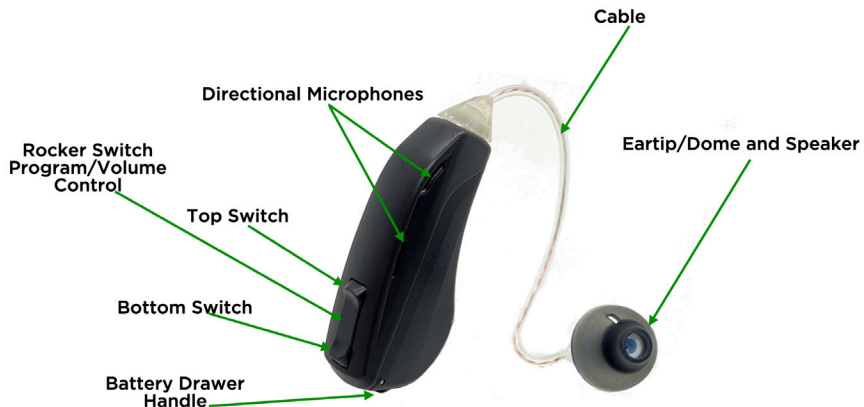
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Hearing Aid Parts



Introduction

Congratulations on your new NoviOne RIC hearing aids! Below is a brief introduction to the product and an explanation on how the hearing aids work. Delivered in this little hearing package is a state-of-the-art set of digital signal processing features based on the latest advances in hearing science. The product has been finely tuned by us to create an elite listening experience. NoviOne was created for the Direct-To-Consumer market to deliver pre-programmed hearing aids for adults with mild to moderate hearing loss.

Battery Drawer Functions

The battery drawer has three positions: ON (fully closed), OFF (partially open), and OPEN.



Fully closed position is the ON position. When the battery drawer is in the fully closed position with a functioning battery installed, it will power on and be ready to use.

The OFF position of the battery drawer is located between fully closed and fully open. It is used to turn the hearing device OFF without allowing the battery to fall out of the device. When the device is not in use, use the battery drawer handle to open the battery drawer to the OFF position. This will avoid draining the battery and extend the battery life. This is especially important to do before you go to sleep at night. It is acceptable to completely open the battery drawer as well.

The OPEN (fully open) position should be used when changing the battery. In this position, the battery is accessible for removal and replacement.

Installing the Battery

Before using your hearing aids, a battery **must** be installed.

1. Using the battery drawer handle, open the battery drawer to the OPEN position.
2. Take a brand new #312 battery, remove the tab from the battery, and place the battery into the battery drawer with the rounded side down into the battery drawer. The flat side of the battery should be up.
3. Push the battery drawer closed to the ON (fully closed) position by pressing on the battery drawer handle past the first click until the battery drawer is completely shut.
4. The hearing aid automatically powers on, after a five second delay, when the battery drawer is in the fully closed (ON) position. The start up default program is Home and the volume will be at the midpoint.

Step 1



Step 2

Remove brown tab



Step 3



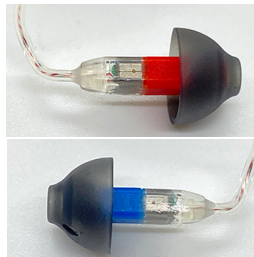
Right and Left Device Indicators

The right device is indicated by the color **red** on the speaker.

The left device is indicated by the color **blue** on the speaker.

Inserting and Removing the Hearing Aids

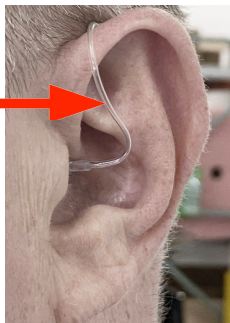
1. Place the hearing aid behind your ear and hold it in place.
2. Using the other hand if needed, gently insert the eartip/dome into your ear canal until the cable rests against your head.
3. Ensure the eartip/dome is seated securely, all the way in your ear and the device is resting comfortably behind your ear. The cable will prevent you from pushing the eartip/dome into your ear too far.



Correct



Incorrect



Removing the Hearing Aids from Your Ears

1. Grasp the cable with your thumb and finger.
2. Gently pull the cable directly outward to remove the cable out of your ear canal.
3. Remove the hearing aid from behind your ear.



Fitting Your Hearing Aids

For best results, the hearing aids should fit properly on and in your ears.

Fitting Your Eartip/Dome:

First, check the fit of your eartip/dome. Your hearing aids come preinstalled with the size medium closed eartip/dome. In the box, you will find size small, medium, and large eartip/domes in both open and closed types (see pg 7 “Eartip/Dome Types” for details).

A properly fit eartip/dome should feel stable and comfortable in your ear. It should be snug, but should not feel tight.

If the eartip/dome backs out of your ear or moves inside your ear canal, try a larger size.

If you are experiencing feedback or whistling, try a larger size closed dome.

If the eartip/dome feels tight or causes discomfort in your ear, try a smaller size.

If the eartip/dome feels like it gets “stuck” when you insert the device, try a smaller size.

Eartip/Dome Types

Your hearing aids come with two different types of eartips/domes: 1) open; 2) closed. Open eartips/domes have airholes; closed domes have smaller openings. Your hearing aids come preinstalled with the size medium closed domes.

Closed domes give fuller, richer sound. They allow for higher volume without feedback or whistling.

Open domes may cause feedback or whistling in some ear canals, especially if you turn up the volume. However, they can help keep your ear from feeling “plugged.”

- If your ear feels “plugged,” try the open dome.
- If sounds are loud or “boomy,” try the open dome.
- If sounds aren’t loud enough, try the closed dome.
- If you are experiencing feedback or whistling, try the closed dome. If you are using a closed dome and still experiencing feedback, try a larger size closed dome (see pg 6 for details)
- If sounds are “tinny,” try the closed dome.

In addition to selecting the correct dome type, you will need to ensure you have selected the right size dome for your ear. See pg 6 “Fitting Your Eartip/Dome” for details.

Closed



Open



Fitting Your Cable

Next, you should check the fit of the cable. Your hearing aids come preinstalled with the size medium cable. The size medium cable fits most ears.

Your cable should lie flat against your face with the hearing aid resting comfortably over the top of your ear. See pg 5 for correct placement of the hearing aid on your ear.

You may need a larger size cable if: 1) the hearing aid falls forward off your ear; 2) the cable feels tight or pulls along the front of your ear.

You may need a smaller size cable if: 1) the hearing aid falls backward off your ear; 2) the hearing aid is loose on your ear and moves when you shake your head or open and close your mouth.

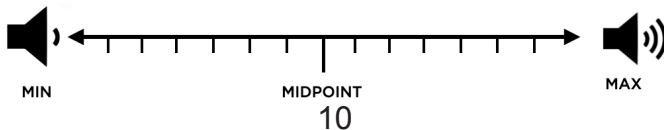
Call customer service to order a different size cable: (763) 231-6591

Adjusting the Volume & Programs with the Rocker Switch

The rocker switch is used to change the volume and programs of the device.

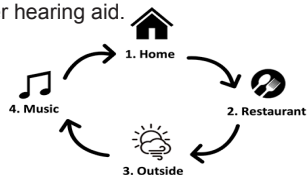
Volume Control

To increase the volume, press and release the top switch quickly. To decrease the volume, press and release the bottom switch quickly. A tone/indicator will sound when the volume changes. A triple beep or voice indicator will play when the minimum/maximum volume has been reached. The volume will reset to "Midpoint" when the hearing aid is turned on. The volume control is adjusted via ear-to-ear synchronization; adjusting the volume on one hearing aid will automatically adjust the other hearing aid.



Programs:

Programs are designed to provide additional benefit in certain listening situations, but you don't need to change programs to hear well. When you turn on your hearing aids, they are in the Home program. The Home program is designed to help in all listening situations. To select the next program, press and hold for one second on the top switch, then release. To select the previous program, press and hold the bottom switch for one second and release. A beep or voice alert will play when the button has been pressed long enough. A voice indicator will play indicating the program that has been selected. The programs are adjusted via ear-to-ear synchronization; adjusting the program on one hearing aid will automatically change program in the other hearing aid.



Home: Good for all-around listening. Noise reduction is on at a medium-low setting.



Restaurant: Good for use in noisy situations. Sounds in front of you are amplified and sounds behind you are reduced—remember to look in the direction where you want to listen. Noise reduction is on at a high setting.



Outside/Car: Good for listening outside, especially in wind, or in a car with road noise or windows down. Noise reduction is on at a high setting.



Music: Good for listening to music in a room, concert, auditorium, or theater. May provide benefit for television, lectures, or worship services. This setting provides a boost to both bass and treble sounds. Noise reduction is on at a medium setting.

Mobile App Controls:

You can use the Novidan mobile app to choose programs, adjust hearing aid volume, adjust streaming volume (for Apple iOS only), and adjust sound quality settings.

To adjust programs, select your desired program tile from the four program tiles on the main screen. Selecting the program tile will set both hearing aids to your chosen program.

To adjust hearing aid volume, drag the volume slider. Drag the slider up to increase volume and drag it down to decrease volume. The number value will show you your selected volume level. Tap the binaural link button to adjust both ears together. Untap the binaural link button to adjust each ear independently.

To adjust streaming volume, drag the streaming volume slider. This control will adjust the volume of streamed media for Apple iOS only. See Streaming section below for details.

Using the Mobile App to Adjust Sound Quality:

The mobile app can be used to adjust the sound quality of your hearing aids. Tapping the gear icon on the main screen will take you to the sound quality adjustment screen.

To increase treble, drag up the brightness slider. The brightness slider adjusts the amount of treble, or high-frequency emphasis, in your hearing aids.

To increase bass, drag up the fullness slider. The fullness slider adjusts the amount of bass, or low-frequency emphasis, in your hearing aids.

To decrease background noise, tap the noise reduction tile.

To make soft sounds louder, tap the whisper boost tile. Whisper boost increases emphasis on soft sounds to help you hear even the quietest sounds around you. Try this option if you are struggling to hear children, soft-spoken individuals, or speech from a distance. Note that whisper boost may make environmental sounds like HVAC and fans sound loud or annoying.

Streaming (for Apple iOS only)

Apple iOS users can receive and play audio from a connected iPhone, iPad or iPod Touch. This may be a phone call, Facetime or other video call, music, television or movie audio, audio books, podcasts, and more.

Use the Streaming Volume slider on the main screen to adjust the volume of streamed content. Drag up the slider to increase the volume of streamed content. Drag down the slider to decrease the volume of streamed content.

Bluetooth Connections:

Your hearing aids have Bluetooth Low Energy and Made-for-iPhone audio streaming built right in, so you can control your hearing aids with your smartphone and hear your phone audio directly in both of your hearing aids. Your hearing aids can be paired with up to 20 different phones or tablets.

To pair your hearing aids, turn on Bluetooth in your phone. Follow the instructions in the Novidan mobile app.

Replacing the Battery

When the battery needs to be replaced, use the battery drawer handle to open the battery drawer to the FULLY OPEN position (see page 4). Remove the dead battery and dispose of it. Take a brand new #312 battery, remove the tab from the battery, and place the battery into the battery drawer with the rounded side down into the battery drawer. The flat side of the battery should be up. Push the battery drawer closed past the first click (OFF position) to the fully closed (ON) position to turn on the device.

Battery Replacement

Each device uses one #312 size zinc-air battery. The package has a brown color indicator. Novidan Batteries are premium quality at an affordable price and can be conveniently ordered from our website. www.novidaninc.com

Replacing the Cable

A cable may be removed to be cleaned or to change sizes. Your hearing aids arrive with medium length cables already installed on the hearing aids. To remove a cable, grab the cable plastic connector and pull straight off (see left figure below). Hold onto the device with one hand and the cable with the other hand, as shown in the right figure below. Pull the cable straight out from the device until it separates from the device.



The cable is installed by holding it by the plastic connector end and pushing it into the hearing aid socket until it is fully seated in the orientation shown below. Double check that the cable is fully inserted into the hearing aid socket.

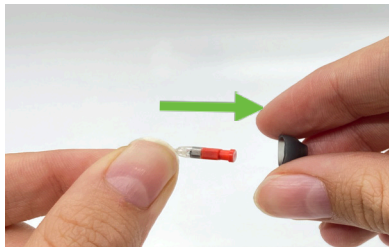


Replacing an Eartip/dome

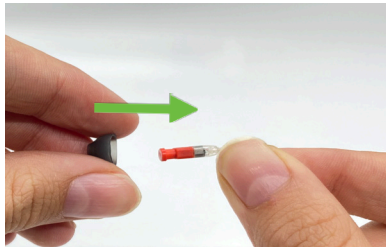
An eartip/dome may be removed to be replaced or to change sizes. To remove the eartip/dome, hold the cable in one hand and pinch the end or side of the eartip/dome with the other hand. Pull the eartip/dome straight out from the barb. See page 7 for more information about eartips/domes.

A new eartip/dome is installed by holding onto the end of the eartip/dome and pushing the eartip/dome over the barb of the speaker. Ensure the eartip/dome is **completely** seated over the barb.

To remove

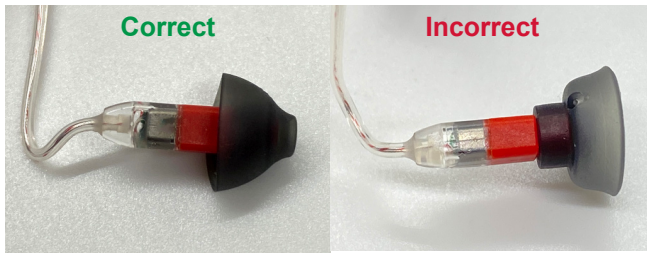


To install



Inspecting the eartips/domes

Double check that the eartip/dome is **completely** seated by gently pulling on it to ensure it is secure before putting the device onto your ear.



Maintenance and Care of the Device

Your hearing aids are designed to resist moisture and perspiration; however, maintenance and care of your device is important to sustaining excellent performance and long life of the device. If your hearing aids are exposed to water, sweat, or excess dust, the device must be cleaned.

Cleaning your Hearing Device

Inspect your hearing device for signs of dirt, earwax, and moisture. Clean the surface of the device with the brush provided in the package.

Cleaning Speaker and Eartips/domes

Eartips/domes should be cleaned daily using a dry tissue or the brush included in your package. Do not use water, soap, or any type of moist cleaning product on any part of your hearing aid. Properly maintained eartips/domes should last you months. If you notice your eartip/dome is damaged or torn, stop using it immediately. Replace the damaged eartip/dome or call customer service to order replacement eartips/domes: (763)231-6591



Device Storage

The device should be stored in a dry place at room temperature with the battery drawer in the OFF or OPEN position when the device is not being used. The battery should be removed for any long-term storage.

Operating Conditions

The device can be operated in the following environmental conditions:

Temperature not to exceed 122F. Humidity not to exceed 95% rH

This device is classified as IP57 (depth of 1 meter for 60 minutes). It is designed to withstand daily life (mild rain, perspiration). It is not intended to withstand liquids with chemical content such as detergents, chlorinated water, soap, hair spray, makeup, cosmetics or saltwater. Do not immerse your hearing device in water.

Conditions Causing Adverse Effect

Avoid excessive vibration, mechanical shock, and dropping your device on hard surfaces. Avoid exposure to excessive heat, humidity or water. These conditions may damage your device and void the warranty.

Children with Hearing Loss

This device cannot be used for children under the age of 18 years old.

Keep Out Reach of Children and Pets

Pets love to chew on and eat hearing aids. Batteries are harmful if swallowed by children or pets.

Warnings

Consult a physician if any irritation, discomfort, accelerated accumulation of cerumen or other side effects result from using your hearing aids.

Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases, infrequent use of a hearing device does not permit a user to attain full benefit from it. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

This device should be not used as a sole safety measure where lack or inability to hear may result in serious injury or death. Although the hearing aids are built to a high level of quality and reliability, they are not designed as a life sustaining device.

When increasing your hearing aid volume, slowly increase until the volume is comfortable.

Wireless Information

Wireless Connectivity: The hearing aid uses Bluetooth technology to communicate with a paired smart device and to communicate between the left and right hearing aid.

The hearing aids should not be used in areas that prohibit the use of electronic or wireless devices.

Regulatory and Legal Information: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by Novidan, Inc. could void the user's authority to operate this equipment.

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. This device complies with FCC radiation exposure limits set forth for the general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Model: Kamen Wireless

FCC ID: 2AXQ3G1P1

Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.

Radio Transceiver Frequency Range: 2.4 to 2.4835 GHz

Radio Receiver Bandwidth: 2 MHz

Modulation Type: 1 Mb/s and 2 Mb/s GFSK

Peak Effective Isotropic Radiated Power: 0 dBm

This equipment has been tested and found to comply with the limits per CISPR 11 class B.

Peak Effective Isotropic Radiated Power: 0 dBm

This equipment has been tested and found to comply with the limits per CISPR 11 class B.

Electromagnetic Emissions			
The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure that it is used in such an environment.			
Emissions Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	Group 1	The hearing aid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B	The hearing aid is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

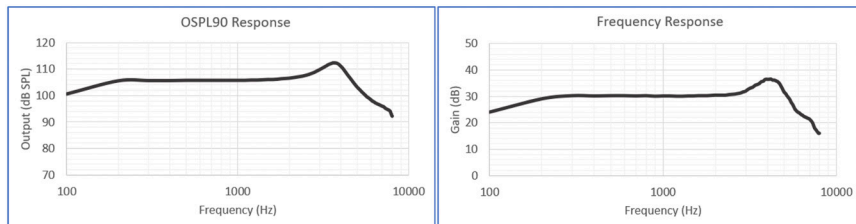
Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should ensure that it is used in such in an environment.		
Immunity Test	IEC60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
Radiated RF EM Fields IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz

Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz
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Technical Data

Product Performance



	2cc Coupler (Typ/Max)	
Peak Output / HFA-OSPL90 (dB SPL)	113 / 106	
Peak Gain / HFA-FOG50 (dB)	35 / 30	
Reference Test Gain (dB)	29	
Frequency Range (Hz)	<200 – 8000	
THD (%)	0.5	< 1
EIN (dB SPL)	23	< 27
Battery Current (mA)	1.4	< 1.6
Battery Life (days)	5 - 7	6 - 8

Typical performance with closed domes in Test Mode per ANSI s3.22. Actual battery life depends on volume setting, listening environment and battery quality. All data is subject to change without notice product improvements.

Troubleshooting

Issue	Possible Remedies
Dead, hearing aid does not turn on, no sound	1. Ensure battery drawer is completely closed 2. Replace battery 3. Check speaker for wax clogging the opening. If present, clean with the wax guard tool or use the brush to clean out the wax. 4. Check eartip/dome for earwax or other debris. If material is present, clean the dome with the brush or replace the dome. See pg. 13 for details.
Weak sound	1. Check eartip/dome and speaker for earwax or other material clogging the opening. Clean with wax guard tool or use the brush to clean out the wax.
Own voice sounds loud, hollow or “in a barrel”	1. Change eartip/dome to the open style eartip/dome. See pg. 7 for details.
Feedback or whistling	1. Ensure device is properly inserted. 2. Ensure proper style and size dome is in use. Try a larger size, closed style dome. See pg. 6-7 for details. 3. Remove clothing, or other objects near ear
Too much background noise	1. Select a different program 2. Turn down the volume
Too loud	1. Turn down the volume 2. Try an open style dome. See pg 7 for details. 3. Select a different program
Doesn't fit and/or doesn't stay in ear	1. Check that the hearing aid is properly inserted. See pg. 5 for details. 2. Check that you are inserting the correct hearing aid in the correct ear. See pg. 5 for details. 3. Try a different size dome. See pg. 6 for details. 4. Try a different size cable. See pg. 8 for details.

Service and Warranty

The hearing aids come with a 1-year limited warranty against manufacturing defects. The warranty does not cover hearing aids that are damaged, misused, abused or physically altered (including unauthorized repairs). This also includes removal or tampering with the serial number label. The warranty is also void if any other brand cable or eartip/dome are used on this device. Please only use NoviOne parts.

Hearing Aid Repair

Contact Novidan, Inc. for information on how and where to obtain repair service or extra eartips/domes and cables. Also feel free to call us to order additional parts, accessories and batteries.

CONTACT:

763 231 6591

sales@novidaninc.com

Important Information from the FDA

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. (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.

CONTACT

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