

Mach I OTC Hearing Aids

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- · You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

Caution: This is not hearing protection.

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

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

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

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

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part further into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: If you remain concerned, consult a professional. If you try this device and continue to struggle with or re-

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

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

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

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

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

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

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc. Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

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1 Getting Started

Congratulations on purchasing your new Mach I OTC Hearing Aids! In this user manual is a brief introduction to the product and an explanation on how your hearing aids work. Delivered in these little hearing aids are state-of-the-art digital signal processing features based on the latest advances in hearing science. This product has been finely tuned by us to create an elite listening experience.

What's in the Box



Hearing Aids (1 Pair)



8 Size 312 Batteries (1 Pack)



Open Eartips



Medium



Large (2) (2 Installed)

Closed Eartips









Small (2) Medium (2) Large (2)

Thin Tubes



Small (2)

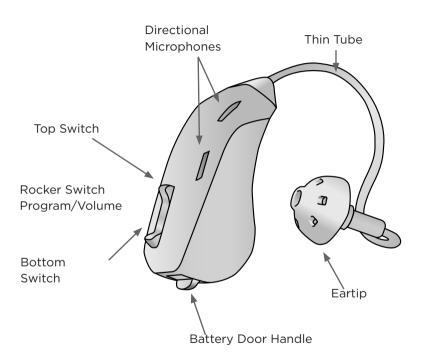


Medium (2 installed)



Large (2)

Hearing Aid Parts



Battery Door Positions

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







ON Position

OFF Position

OPEN Position

The **ON** position is when the battery door is fully closed. When the battery door is in the fully closed position with a functioning battery installed, your hearing aid will power on and be ready to use.

The **OFF** position of the battery door is located between fully closed and fully open. It is used to turn your hearing aid **OFF** without allowing the battery to fall out of your hearing aid. When your hearing aid is not in use, open the battery door 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 door as well.

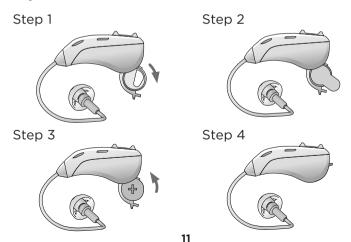
The **OPEN** position is when the battery door is fully open. When the battery door is fully open, the battery is accessible for removal and replacement.

Installing the Battery

Before using your hearing aids, a size 312 battery must be installed. The package usually has a brown color indicator.

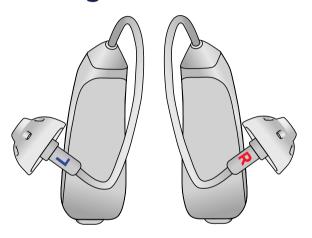
- 1. Using the battery door handle, open the battery door to the **OPEN** position.
- 2. Place the 312 battery, with tab side up, into the battery door.
- 3. Remove the tab.
- 4. Fully close the battery door to turn your hearing aid on.

Note: When your hearing aid is not in use, pull the battery door open to the **OFF** position (refer to page 10). When battery is low, a voice indicator will sound.



Setting Up Your Hearing Aids

Left and Right Indicators



The left hearing aid is indicated by "L" printed on the thin tube.

The right hearing aid is indicated by "R" printed on the thin tube.

Inserting Your Hearing Aids in Your Ears

- 1. Place your hearing aid behind your ear and hold it in place.
- 2. Using the other hand if needed, gently insert the eartip into ear canal until the thin tube rests flat against your head.

<u>A</u> Caution: Do not insert the eartip past this point. Do not force the eartip further down into the ear canal than the depth allowed by the bend in the thin tube.

3. Ensure the eartip is seated all the way in your ear securely and your hearing aid is resting comfortably behind your ear.





Physical Fit of Your Hearing Aids

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



Removing Your Hearing Aids from Your Ears

- 1. Grasp the thin tube with your thumb and finger.
- 2. Gently pull the thin tube outward to remove eartip from your ear canal.
- 3. Remove your hearing aid from behind your ear.



Selecting Eartip Size

Your hearing aids come with the medium size open eartip pre-installed. In the box you will find size small, medium, and large eartips in both open and closed types (refer to page 16).

A properly fitting eartip should feel stable and comfortable in your ear. It should be snug but should not feel tight.

Open Eartips Small (2) Medium (2 Installed) Closed Eartips Small (2) Medium (2) Large (2) Large (2) Large (2)

Try a **larger** eartip if...

- The eartip backs out of your ear.
- The eartip moves inside your ear canal.

Try a **smaller** eartip if...

- The eartip causes discomfort in your ear.
- The eartip feels tight inside your ear canal.

Selecting Eartip Type

Select the correct eartip type. Your hearing aids come with size medium open eartips pre-installed.

Closed eartips give a slightly fuller sound. They allow for higher volume without feedback or whistling.

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



Open Eartip

Try the **open** eartip if...

- Your ear feels "plugged."
- Sounds are loud.
- · Voices are "boomy."



Closed Eartip

Try the **closed** eartip if...

- You are experiencing feedback or whistling.
 Try a larger closed tip if feedback or whistling continues (refer to page 15).
- Sounds are "tinny."
- Sounds are not loud enough.

Selecting Your Thin Tube

Your hearing aids come pre-installed with the medium thin tube. The size medium thin tube fits most ears.



Your thin tube should lie flat against the side of your face with your hearing aid resting comfortably on your ear. Refer to pages 13 and 14 for correct placement of your hearing aids

You may need a larger size thin tube if...

- Your hearing aid sits too far forward on your ear.
- The thin tube feels tight or pulls along the front of your ear.

You may need a smaller size thin tube if...

- Your hearing aid sits too far behind your ear.
- Your hearing aid is loose on your ear and moves when you shake your head or open and close your mouth.

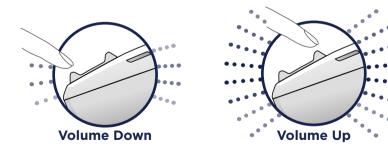
Call customer service at (833) 668-4326 to request a different size (refer to page 31).

Adjusting the Volume & Programs

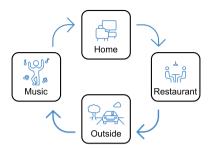
To adjust the volume or program on your hearing aids you can use the rocker switch on your hearing aid. The volume and program control using the rocker switch must be individually adjusted for each hearing aid.

Rocker Switch Volume Control

Quick press the top or bottom switch for less than 1 second, then release to adjust volume; the top switch will adjust volume up and the bottom switch will adjust volume down. A tone/indicator will sound when the volume changes. A voice indicator will play when the minimum/maximum volume has been reached. The volume on your hearing aids will power on to the last setting used.



Programs



Home: All-around listening.

Restaurant: Noisy situations. Sounds in front of you are amplified and sounds behind you are reduced.

Outside/Car: Listening outside, especially in wind, or in a car with road noise or windows down.

Music: Listening to music in a room, concert, auditorium, or theater. May provide benefit for television, lectures, or worship services.

Rocker Switch Program Control

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 always power up to the Home program. The Home program is designed to help in all listening situations, in particular in quieter environments such as watching TV or in small groups.

To select the next program, press and hold for more than 2 seconds on the top switch, then release. To select the previous program, press and hold the bottom switch for more than 2 seconds and release. A program voice alert will play when the button has been pressed long enough. A voice indicator will play indicating the program that has been selected.





Care and Maintenance

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

Cleaning Your Hearing Aids

Inspect your hearing aids for signs of dirt, earwax, and moisture. Clean the eartips and surface of your hearing aids daily with the brush provided in the package. Use the loop end on the brush to clear any blockage present. If the thin tube is visibly dirty it can be cleaned by inserting the thin tube cleaning wire all the way through the thin tube. Do not use water, soap or any type of moist cleaning product on any part of your hearing aid.

Brush Here







Component Replacement Recommendations

It is recommended that you replace your eartips every 3 months. If you notice your eartip is loose, damaged, torn or plugged with ear wax, replace the eartip immediately.

It is recommended that you replace the thin tubes annually. If sound is distorted or intermittent, replace the thin tube immediately.

Please dispose of used batteries, hearing aids and hearing aid accessories properly following local regulations.

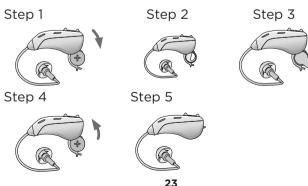
Refer to page 31 to order replacement components.

Replacing the Battery

Each hearing aid uses one 312 size zinc-air battery. The package usually has a brown color indicator. A low battery indicator will sound when the battery is low. Refer to page 31 to order replacements.

- 1. Using the battery door handle, open the battery door to the **OPEN** position (refer to page 10).
- 2. Remove the dead battery and dispose of it properly following local regulations.
- 3. Place a new 312 battery, with tab side up, into the battery door.
- 4. Remove the tab.
- 5. Fully close the battery door to turn your hearing aid **ON**.

Note: When your hearing aid is not in use, pull the battery door open to the **OFF** position (refer to page 10).



Replacing the Thin Tube

Your hearing aids arrive with medium length thin tubes already installed. Refer to page 17 to select your thin tube size. If you need a new thin tube refer to page 31.

To remove a thin tube, hold onto your hearing aid with one hand and the thin tube with the other hand and rotate the thin tube 180 degrees. Pull the thin tube straight out until it separates from your hearing aid. It may take some force to pull it off.



The thin tube is installed by holding it by the plastic connector end and pushing it over the gold connector until it is fully seated in the orientation shown below. Ensure that the thin tube is fully seated over the gold connector before placing the device onto your ear.

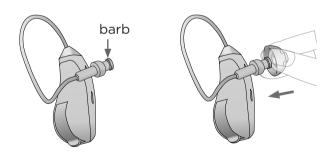




Replacing an Eartip

An eartip may be removed to be replaced or to change sizes. To remove the eartip, hold the thin tube in one hand and pinch the end or side of the eartip with the other hand. Pull the eartip straight out from the barb. Refer to pages 15 and 16 for more information about eartips.

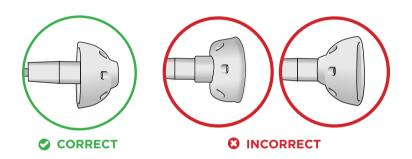
A new eartip is installed by holding onto the end of the eartip and pushing the eartip over the barb. Ensure the eartip is completely seated over the barb.



Inspecting the Eartips

Double check that the eartip is completely seated by gently pulling on it. Ensure it is secure before putting the eartip into your ear canal.

Caution: The eartip could get lodged in your ear canal if the eartip is not installed correctly.



Hearing Aid Storage

Your hearing aids should be stored in a dry place at room temperature with the battery door in the **OFF** or **OPEN** position when your hearing aids are not being used. Refer to page 33 for information on storage conditions for your hearing aids.

Hearing Aid Troubleshooting

Issue	Possible Remedies
Does not turn on, no sound	 Ensure battery door is completely closed. Replace battery (refer to page 23). Make sure to remove battery tabs and place in battery door correctly. Check battery orientation if its difficult to close the door.
	4. Inspect the eartip for earwax or other material clogging the opening. Use the brush and loop to clean out the blockage (refer to page 21).
Own voice sounds loud, hollow or "in a barrel"	1. Change eartip to the open style eartip (refer to page 16).

Issue	Possible Remedies		
Too much background noise	Select Restaurant or Outside program (refer to page 19).		
	2. Turn down the volume (refer to page 18).		
Feedback or whistling	Note: Your hearing aids may whistle or chirp at times when first powered on, when changing settings or if objects get near your ears. Your hearing aids are designed to adapt to changes over time to stop the whistle. If it persists, try the following:		
	 Ensure hearing aid is properly inserted. Remove and re-insert hearing aid (refer to pages 13 and 14). 		
	2. Ensure proper style and size eartip is in use. Try larger size or closed style eartip (refer to pages 15 and 16).		
	3. Turn down the volume (refer to page 18).		
Does not fit and/or stay	1. Check that your hearing aid is properly inserted (refer to pages 13 and 14).		
in ear	2. Check that you are inserting the correct hearing aid in the correct ear (refer to page 12).		
	3. Try a different size eartip (refer to page 15).		
	4. Try a different size thin tube (refer to page 17).		
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Issue	Possible Remedies		
Too loud	1. Turn down the volume (refer to page 18).		
	2. Try an open style eartip (refer to page 16).		
	3. Select a different program (refer to page 19).		
Visible wax	1. Clean your hearing aid (refer to page 21).		
build up	2. Review component replacement recommendations (refer to page 22).		
Unable to	For landline or mobile phone speaker:		
hear your phone call	 Ensure your phone is not pressed against your ear too hard; this can block the microphones on your hearing aids and cause sound to be muffled. 		
	 Try holding your phone speaker slightly above and to the front or back of the hearing aid to align the speaker with the hearing aid microphones. This helps align the speaker to your hearing aid microphones. 		
Weak sound	Inspect the eartip and speaker opening for earwax or debris.		
	2. Turn up the volume (refer to page 18).		

Service and Warranty

Your hearing aids come with a 1-year limited warranty against manufacturing defects. Accessories (i.e. thin tubes, eartips, wax guards, etc.) and cleaning are not covered. 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 thin tube or eartip are used on these hearing aids. Please only use Mach I parts.

Hearing Aid Repair

Contact Sonify Hearing (678 Mendelssohn Ave. N, Golden Valley, MN 55427 or call (833) 668-4326 for information on how and where to obtain repair service or extra eartips and thin tubes. Feel free to call us to order additional parts, accessories and batteries.

Available Replacement Components

We offer:

- Batteries
- Thin Tube Cleaning Wire
- Wax Loop and Brush
- BTE Thin Tube Small (left and right)
- BTE Thin Tube Medium (left and right)
- BTE Thin Tube Large (left and right)
- Open Eartips (small, medium and large)
- Close Eartips (small, medium and large)

Visit www.sonifyhearing.com under the accessories tab to order replacement components.

Contact us at: (833) 668-4326 info@sonifyhearing.com 4

Product Specifications

Operating Conditions

Your hearing aids can be operated in temperatures not exceeding 122°F and humidity not exceeding 95% RH. Your hearing aids are classified as IP57. It is not recommended to immerse your hearing aids in water. They are designed to withstand daily life (mild rain, perspiration). They are not intended to withstand liquids with chemical content such as detergents, chlorinated water, soap, hair spray, makeup, cosmetics or saltwater.

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

Do not share or resell hearing aids.

This product contains magnetic material. Consult your physician on whether this might affect your implantable medical device.

It is recommended to use the product with a secure network

Conditions Causing Adverse Effect

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

Storage Conditions

When storing your hearing aids for an extended period of time, remove the batteries, close the battery door and place them in the case. Your hearing aids should be kept between -13°F and 158°F with humidity not exceeding 90% RH. Prior to use after long term storage, be sure to let your hearing aids acclimate for 1 hour to an ambient temperature of 68°F.

Features

Category	Mach I OTC Hearing Aids
Fixed or Level-Dependent Frequency Equalization	Have fixed frequency equalization that is adjusted via user controls.
Level-Dependent Gain/Compression	Have multi-channel, wide dynamic range compression to make soft sounds louder without making loud sounds too loud.
Noise Reduction	Have multi-band active noise reduction to make continuous noises (like fans, motors, road noise, etc.) less loud.
Signal-to-Noise Ratio Enhancement	Have directional microphones to emphasize sounds from in front, making conversations in noisy places easier.
Feedback Control	Have an adaptive feedback canceller to reduce feedback (whistling).

Category	Mach I OTC Hearing Aids
Personalization	Are customized by the user for selectable acoustic environments (Programs) from hearing aid rocker switch. User's hearing thresholds are not required to personalize the settings.
Coupling to the Ear	Have soft, user-selectable, open and closed eartips to adjust for fit and sound quality.

Features per ANSI/CTA-2051:2017.

Technical Data

Specification	Value	Units
Maximum Acoustic Output	115	dBSPL
Fitted OSPL90/100	97 / 103	dBSPL
Full On Gain	34 Max/27 HFA	dB
Total Harmonic Distortion + Noise	1 - 2	%
Self-generated Noise	27	dBA
Latency	5.8	ms
Frequency Response Bandwidth	100-5000	Hz
Estimated Battery Life	6-8	Days

All measurements per ANSI/CTA-2051:2017. Actual battery life varies with user's volume setting, and battery quality.



Safety, Regulatory and Legal Information

Keep Out Reach of Children and Pets

Keep and store hearing aids, batteries, and accessories out of the reach of children and pets. These hearing aids is not intended to be used for children under the age of 18 years old. These small parts may be a choking hazard, Battery ingestion can cause serious harm.



Warnings and Cautions

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 aid does not permit a user to attain full benefit from it. The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lipreading.

These hearing aids should be not used as a sole safety measure where lack or inability to hear may result in serious iniury or death.

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WARNING: Avoid use of this hearing aid adjacent to other equipment, other than as instructed in this user manual, because it could result in improper operation. If such use is necessary, observe the hearing aids and the other equipment to verify that they are operating normally.

WARNING: Use of accessories, transducers and thin tubes other than those specified or provided by the manufacturer of this hearing aid could result in increased electromagnetic emissions or decreased electromagnetic immunity of this hearing aid and result in improper operation.

WARNING: Do not use accessories, detachable parts or materials not described in the user manual. If unauthorized components are used, it could result in the improper function of the device.

WARNING: Keep small parts and batteries out of children's reach. Small parts may be a choking hazard. Ingestion of batteries can cause bodily harm.

<u>CAUTION:</u> Check first before using the hearing aid systems in areas where electronics are restricted.

CAUTION: Do not use the device if the device or package is damaged.

CAUTION: It can be unsafe to interconnect the hearing aid with other equipment not described in the user manual.

CAUTION: The specific hearing aid shall only be used by the intended person and not by others.

CAUTION: Do not to use the hearing aid in explosive or oxygen-enriched atmospheres.

CAUTION: Only connect hearing aid to equipment that conforms to relevant international safety standards.

CAUTION: No modification of this equipment is allowed.

CAUTION: In the event of a battery leak, do not allow the liquid to make contact with skin or eyes; if contact is made, seek medical attention.

Intended Use

The Mach I OTC Hearing Aids are an air conduction hearing aid intended for use and customization by individuals 18 years and older with perceived mild to moderate hearing impairment.

Indications for Use

The Mach I OTC Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is customized by the user to meet the user's hearing preferences. No preprogramming or hearing test is necessary. The device is intended for over-the-counter sale and use without the assistance of a hearing care professional.

Validation Data

In a user validation study, the majority of the participants reported that the technology contained in the Mach I OTC Hearing Aids is easy to use and improved their ability to hear in noisy environments; the sound quality is clear and it is comfortable to wear all day.

Legal

Sonify Hearing and Sonify Hearing logo are trademarks of Novidan, Inc. Mach I is a trademark of Novidan, Inc.

Please read and retain all user instructions and safety information.

Symbols and Descriptions

⚠ Caution

ng Magnetic Material

⚠ Warning

Choking Hazard

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.

Mach I OTC Hearing Aids

Contact us at: (833) 668-4326 info@sonifyhearing.com www.sonifyhearing.com

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