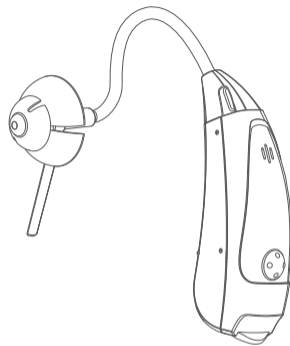


Vivitone®

Vivitone®



support@vivitone.com

CE 0482 FDA MED/CERT

Version: A1

APP-CONTROLLED HEARING AID

# User Manual

Smart



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Thank you and welcome to VIVTONE most innovative and reliable product, designed to enhance the quality of sounds in your everyday life!

This user manual only applies to the Smart, behind-the-ear (BTE) hearing instrument. It can be controlled by the program switch or controlled by Bluetooth mobile phone. For more details, please refer to SOUNDWEAR user guide.

#### Intended use







This BTE Hearing instrument is an electronic device which amplifies sounds from the surrounding environment. It will help people with mild to moderate hearing loss or those who just want to enhance their ability to hear conversations in a noisy environment.

#### Precautions


For users with ear infection, it is suggested not to wear hearing instrument until ear normal condition restored or by following a doctor's advice. Please consult with your hearing healthcare professional first if you have any questions about your hearing or your hearing instrument.

#### Hazard warnings and product safety

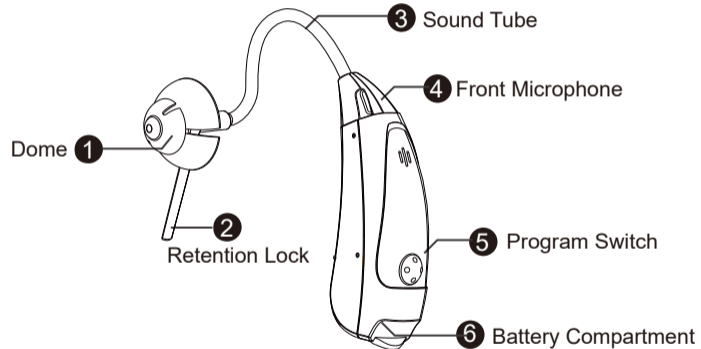
– Please read before using your hearing instrument the first time.

	 Hazard Warnings – relevant warning notices
	Never wear other people's hearing instrument! It could permanently damage/affect your hearing.
	Avoid direct contact with force (e.g. smacking/slapping, wrestling or likewise sports) while wearing a hearing instrument, such impact could be harmful to your hearing.
	Do not wear hearing instrument in heavy industrial areas (mines, explosion sites).
	If pain, skin irritation in the ear or excessive accelerated earwax, consult physician.
	In the unlikely case of the dome being stuck in your ear canal, after the removal of the sound tube from the ear, it is highly recommended, for you to see a physician for safe removal of the dome.

	<p>ⓘ Product Safety – relevant product handling and care</p>
ⓘ	<p>Do not drop hearing device onto a hard surface that can damage the instrument.</p>
ⓘ	<p>To obtain best performance from your hearing instrument, always use new and high-quality batteries.</p>

	<p>Proper disposal of electronic products protects the health of people and the environment. This symbol means the hearing instrument may not be thrown away as normal daily waste. Hearing instrument should be disposed at intended electronic waste/recycle sites, or at your hearing care professional office.</p>
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## Features



# Preparation

## Kit packaging included:

Smart hearing aid	Left tube
User manual	Right tube
Cleaning tool	Domes

## Battery helpful tips

Smart hearing aid uses a 13A battery.

**IMPORTANT:** Insert battery in to the battery door compartment with the positive(+) side (flat side) faced up. If the battery is inserted incorrectly, the door will not close. Do not force to close the battery door.



**WARNING:** Keep batteries away from children and pets. Seek immediate medical attention if a battery is accidentally swallowed!

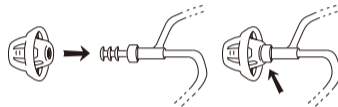
# Operation

## Complete hearing instrument assembly

Instrument, sound tube and dome assembly:

Your hearing instrument consists of three basic parts: The hearing instrument housing, sound tube and dome.

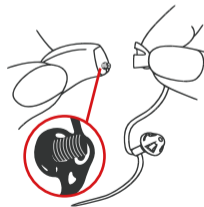
1. Align dome opening and press over the grooves of sound tube, secure proper fitting.
2. Align and tightening the sound tube opening to the instrument's threaded connector clockwise, secure proper fitting.



**Note:** LEFT and RIGHT hearing instrument is provided with the sound tube of the appropriate side.

**RED** lettering on sound tube is for **right ear**

**BLUE** lettering on sound tube is for **left ear**



## How to wear the instrument

1. Place the hearing instrument over the top of your ear.
2. Hold the tube close to the dome with the thumb and forefinger. Insert the dome with gentle pressure into your ear canal until the tube sits flush against the side of the face. The dome should fit in the ear canal snug, but not tight.
3. Using the index finger, tuck the retention lock into the edge of the bowl of the ear just above the area of the ear lobe.

NOTE: Turn on the hearing instrument before inserting dome into the ear canal. Keep volume at low or comfortable setting; but not loud, to avoid feedback effect.



1



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## On and off function

### Turn on

Gently insert battery and close the door. The hearing instrument has built-in power on delay, so it will take several seconds for the device to activate its full functions.

### Turn off

Simply keep battery door open.  
This also helps extend battery life.



## Volume control

Both volume and selection program can be adjusted by memory switch, as well as by Bluetooth. For learn how to connect and use Bluetooth mode, please refer to the app user manual.



## Program switch

Your hearing instrument can be programmed up to 4 different listening programs. When the hearing instrument is turned on, it will revert to last program setting. Other preset programs are for your specific needs that can be accessed by using the program switch. Pressing of the program switch will change the program according to the preset sequence: 1, 2, 3 and 4.

Your hearing instrument 'beeping' signal will help identify preset programs. Example: program 1 will emit 1 beep, program 2 will emit 2 beeps, etc.

Your Smart is preset with 4 different listening programs.

Program 1	Program 2	Program 3	Program 4
Conversation environments, such as home and office use. High fidelity and low noise reduction.	Noisy environments, such as restaurants. Higher noise reduction.	Traffic environments, strengthen the sound of your surroundings	Outdoors. Noise reduction focused for wind.

# Maintenance

## Troubleshooting

No/Low Sound Amplification	
POSSIBLE CAUSE	SOLUTION
Low battery	Replace with a new battery
Built-up wax in the dome	Clean the dome or replace the old dome
Excessive ear wax	Consult your physician
Volume set too low	Turn up the volume
Improper dome insertion	Re-insert the dome
Hearing instrument damaged	Contact your provider
Hearing change	Contact your hearing care professional
Whistling or Feedback	
Dome is wrong size or damaged	Replace with new or better fitting dome
Improper dome insertion	Re-insert the dome into your ear so that it is flush with the walls of the ear canal

## Whistling noise helpful tips

Whistling is common in small amplifier and is known as 'feedback'. It is caused by amplified sound leaving the ear and receiving back into the microphone and being re-amplified. The following tips will help reduce the effect of feedback/whistle noise:

1. Lower the volume.  
Keep volume at lower setting before inserting the instrument in your ear.
2. Secure instrument fitted position  
Feedback/whistling noise will stop when the instrument is best fitted/sealed in the ear with the best fitted dome size.
3. Clear the ear canal of wax or debris.  
Seek your hearing care provider for excessive wax built-up
4. Replace the dome or tubing.  
Change new dome with a better fitted size.  
Make sure the tubing is not broken or torn.

## Sound tube cleaning and care

### Care of sound tube

Use a soft cloth to remove any dirt and moisture after each used. The provided cleaning tool and brush is for removing debris / wax built-up inside the sound tube and dome.

### Replace and cleaning of sound tube

1. To replace - rotate the sound tube counter-clockwise from the hearing instrument case until loosening for removal.
2. To clean - insert the cleaning tool through the threaded end of the tube, push the cleaning tool all the way through the tubing until the tip of the cleaning tool comes through the end of the dome.





- To reassemble the sound tubing, simply reverse the removal process by tightening the tubing and the instrument connector with a clockwise motion until the two flat surfaces are flushed together.



### Replacing the battery

- Switch off the hearing instrument by opening the battery door.
- Remove the old battery.
- Remove the protective foil from the new battery.
- Insert the new battery, be sure that the Plus(+) is facing up.
- Close the battery door.

Important: Handle the battery door gently. The operation requires only a minimum force. If there is any resistance when closing the battery door, check to see that the battery is correctly inserted. The battery door cannot be closed if the battery is inserted incorrectly.

### Cleaning care and precautions

Keep the hearing instrument clean and dry. Use only soft cloth to remove any body oil or moisture from the hearing instrument shell. Use provided cleaning tools to clean wax built-up. If the instrument is subject to a lot of perspiration, it is recommended, turned off the hearing instrument and put into a dry box at least once a week. Dry box can be bought online or any local pharmacy.



- DO NOT** use water, harsh chemicals, strong cleaners or other fluids to clean the hearing instrument.
- DO NOT** leave your hearing instrument in the direct sun or in areas where the temperature can rise over 60°C / 140°F for extended periods of time.
- ALWAYS** handle the hearing instrument with care; it's important to prevent hearing instrument from dropping on hard surfaces, such as counter top, table or floor.

## Environment condition

Environment Condition	Working Condition	Transportation Condition	Storage Condition
Temperature	10℃~+40℃	-20℃~+60℃	-20℃~+60℃
Air humidity	0%~80%	0%~90%	0%~80%
Air pressure	500~1200hpa	500~1200hpa	500~1200hpa

## Technical data

Model	Smart
Peak OSPL 90(dB SPL)	122
HAF OSPL 90(dB SPL)	111
Peak Gain(dB)	38
HAF full on Gain(dB)	29
Total Harmonic Distort:	
500Hz(%)	≤3.0
800Hz(%)	≤2.0
1600Hz(%)	≤2.0
EQ Input Noise(dB)	≤32
Frequency Range(Hz)	300-3900

## FDA information

Good health practice requires that a person with a hearing loss to 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 a Hearing Healthcare Professional 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 healthcare provider 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 Healthcare Professionals 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.

#### Notice to hearing healthcare providers

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, then consult a physician.

- \* Visible congenital or traumatic deformity of the ear.
- \* Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- \* History of active drainage from the ear within the previous 90 days.
- \* Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1000Hz, and 2000 Hz.
- \* History of sudden or rapidly progressive hearing loss within the previous 90 days.
- \* Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- \* Acute or chronic dizziness.
- \* Pain or discomfort in the ear.

Stop using hearing aids and consult a physician if:

- \* Hearing in one or both ears worsened.
- \* Your ear becomes occluded with excessive ear wax.
- \* Hearing does not improve while using the provided hearing aid
- \* You develop an infection in your ear or ear canal.
- \* Skin irritation develops in or around your ear canal.

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.

A hearing aid 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 hearing aid(s) is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lip reading.

### 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. Hearing loss may cause problems in language development, educational growth, and social growth of a child. Training and experience qualify an audiologist to assist in the evaluation and rehabilitation of a child with a hearing loss.



### Manufacturer

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