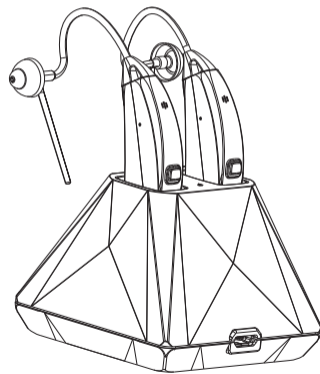


User Manual

Primo MA801



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Preface

Congratulations! Please read this user manual carefully before use.

This user manual only applies to the Primo rechargeable hearing instrument.

Intended use

This Primo MA 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 patients with ear infection, it is suggested not to wear hearing instrument until cured 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.


THE MANUFACTURER RESERVES THE RIGHT TO MODIFY THE TECHNICAL SPECIFICATIONS OF THE PRODUCT WITHOUT ANY PRIOR NOTICE.

Hazard warnings and product safety

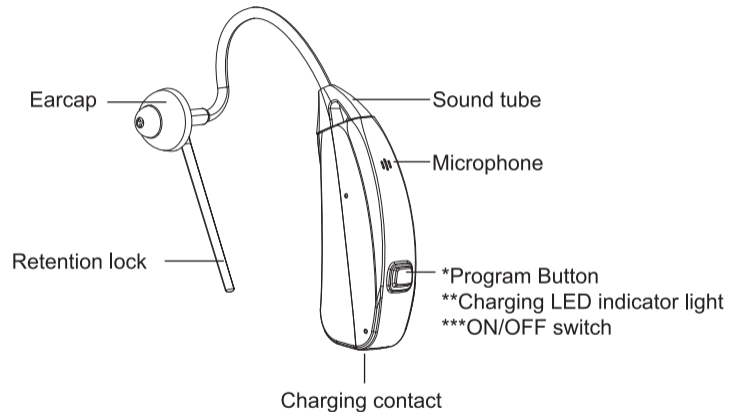
– Please read before using your hearing instrument the first time.

	 Hazard Warnings – relevant warning notices
	Never wear other people's hearing aid! 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).
	Hearing aid batteries are toxic. Keep out of reach of children and pets. If accidentally swallowed, consult physician immediately!
	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.
	All external devices and hearing instrument should meet the standard of EN 60601-1:2006/A2:2021

	i Product Safety – relevant product handling and care
i	Do not drop hearing device onto a hard surface that can damage the instrument.
i	When hearing instrument is not in use, leave battery door open so moisture can evaporate. Store instrument in a safe, dry and clean place.
i	Remove battery from your hearing instrument if not use for an extended period of time to prevent dead battery from leakage/expansion that can be harmful to the instrument.
i	To obtain best performance from your hearing instrument, always use new and high-quality batteries.

	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.
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Features




Preparation

Kit packaging included:

2 x Primo MA	1 x Charging base	2 x Left tube	
1 x User manual	1 x APP manual	1 x AC adapter	2 x Right tube
1 x Cleaning tools	1 x Micro-USB cable	1 x Package of domes	

Battery helpful tips

1. A full charge takes about 3+/-0.5 hours, and will allow up to 18 hours of use.
2. Recharging process will automatically shut off when battery is fully charged.
3. To maximize the extended life of the battery, keep the hearing instrument in the charging base when not in use for an extended period of time.

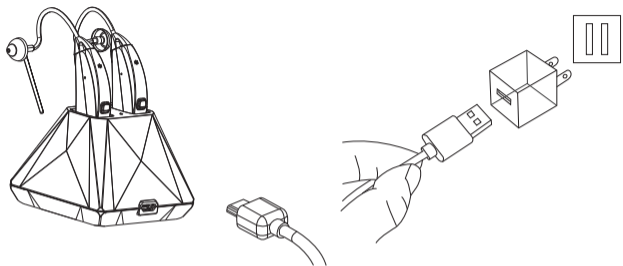
 **WARNING:** Power is supplied by a lithium polymer battery which is built-in feature that should not be removed EXCEPT by an authorized service center. To prevent damage of the instrument, do NOT attempt to replace the built-in battery! Contact the instrument manufacturer or your professional hearing provider for further assistance.

Operation

How to charge

1. Put the hearing aids into the charging base.
2. Use the provided micro USB cable to attach the charging base to a USB power source or a wall jack using the provided AC Adaptor.
3. We recommend that you fully charge the hearing instrument before using it for the first time.
4. When the hearing instrument is placed correctly in the charging base the Program/Memory switch will glow blue to indicate that the hearing instrument is being charged. When the instrument is fully charged the blue LED indicator will turn Green, and will be ready to use.

NOTICE: The indication light on the charging base will shine green when normal working, and shine red means fault.



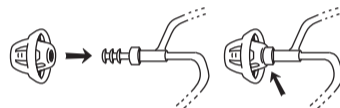
NOITCE: 1. We recommend that the hearing instrument should be fully charged prior to the initial usage. When the instrument is put to use before fully charged, its usage duration will NOT be at its optimal value.
 2. There is no negative effect to the hearing instrument to stay in charging base after fully charged since the advanced circuitry regulates the voltage and monitors the instrument charged condition/status.

Complete hearing instrument assembly

Instrument, sound tube and dome assembly:

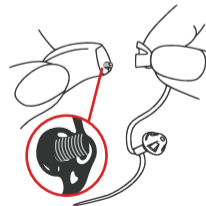
Your hearing instrument consists of three basic parts: The hearing instrument housing, sound tube and dome.

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.

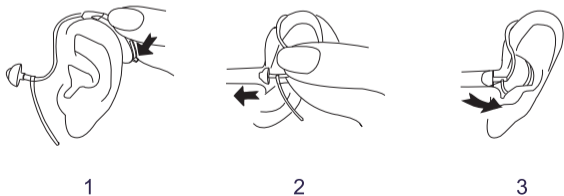
RED lettering on sound tube is for right ear
BLUE lettering on sound tube is for left ear



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.



ON and OFF function

Turn ON/OFF – Press and HOLD the memory switch for about 3 seconds. The device is equipped with power-on delay function, so it needs a few second to get started. When the instrument is turned on, it will flash green, and when it is turned off it will flash blue.

Volume control

All volume, frequency and other sound adjustments are conducted from within the Sound Enhancement portion of the SOUNDWEAR APP.

NOTE: It is recommended, before wearing the instrument, to have the volume start at lower or comfortable setting. High/loud volume set before inserting the instrument into the ear can cause feedback and may be harmful to your hearing.

Memory 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 memory switch. Pressing of the memory switch will change the program according to the preset sequence: 1, 2, 3 and 4. Your Primo MA hearing instrument 'beeping' signal will help identify preset programs. Example: program 1 will emit 1 beep, program 2 will emit 2 beeps, etc.

Standard program setting and recommended using environment:

	Program 1	Program 2	Program 3	Program 4
Primo MA	Normal	Restaurant	Traffic	Outdoor

NOTE: The programs are preset by your hearing care professional or the manufacturer.

Maintenance

Troubleshooting

SYMPTOM	POSSIBLE CAUSE	SOLUTIONS
No/low sound, no function	Low battery	Recharge the instrument
	Built-up wax in the dome	Clean the dome; 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 hearing care professional
	Hearing change	Contact your hearing care professional
Whistling, feedback	Dome wrong size, damaged	Replace with new or better fitted dome
	Improper dome insertion	Re-insert the dome

Charging system functions

1. How to charge the instrument?

Connect the charging base with TYPE-C cable that connect to AC adapter which plug into 120/220V outlet or connect the USB cable directly into computer's USB port or any power supply sources.

2. How long does it take for the device to be fully charged?

It takes approximately 3+/-0.5 hours to fully charged the instrument.

3. How long will the fully charged instrument work until next charge?

Under quiet environment, the fully charged instrument will work up to 18 hours. In some loud surroundings, instrument requires more power to filter out sounds thus it may result in an insignificant shorter usage duration.

4. How to know when the hearing instrument is fully charged?

LED light indicator turns GREEN at fully charged.
LED light indicator stays BLUE during charging process.

5. Why the device is not working during the charging phase?

The instrument will turn OFF automatically to allow faster charging cycle. It is recommended the hearing instrument should turn OFF when not in use to prevent the battery from complete discharged and the unwanted feedback noise.

6. How to maintain the hearing instrument charging system?

To maximize the internal battery usage, it is recommended that the hearing instrument is charged, typically overnight, on a daily basis. It is also recommended that the hearing instrument should turn OFF if not in used for an extended period of time; or place in the charging base connected with the power source.

7. Can the user replace the built-in battery?

Built-in battery cannot be removed or replaced by anyone EXCEPT the authorized service center per manufacturer. Contact your hearing care provider for more information and further assistance.

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.



3. 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.



Low battery warning

When you hear one short beep - signal alerting that battery is running low/out. Low battery alert will continue intermittently until battery gets recharged.

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.

Appendix

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

Technical data	Primo MA
Peak OSPL 90(dB SPL)	116
HAF OSPL 90(dB SPL)	106
Peak Gain(dB)	39
HAF full on Gain(dB)	32
Total Harmonic Distort:	
500Hz(%)	≤2.0
800Hz(%)	≤2.0
1600Hz(%)	≤2.0
EQ Input Noise(dB)	≤26
Frequency Range(Hz)	400-4500
ANSI S3.22-2003	IEC 60118-7/2005

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.

* The applicable age of this product is 6 years old and above. (Children from 6 to 14 years old must use the device under the supervision of adults.)

Service and warranty

Please ask your hearing instrument/care provider, where you purchased your hearing instrument, about the term of the product warranty and service coverage with/without warranty.

DO NOT send your instrument directly to the manufacturer for product service or replacement.



Manufacturer

Xiamen NewSound Technology Co.,Ltd
Address: No.13 of Xiangyue Road,
Torch Hi-Tech Industrial Development Zone,
Xiang'An District, Xiamen, China.



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Germany

