

物料编号：1.4.05.D36AT.001

客户型号：HBE-4/0144

工艺要求	惠州市锦好医疗科技股份有限公司包材文档		
材质：120G双胶纸 工艺：骑马钉 颜色：4色印刷 尺寸：102*146mm 总P数：20P（含封面封底） 正公差：1mm 负公差：0mm	文稿名称：W100 JH-D36AT 定制OTC英文说明书		
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NuvōMed®

DigiEars | PLUS
Digital Behind-The-Ear
Hearing Aid

Model: HBE-4/0144



INSTRUCTION MANUAL

**PLEASE READ ALL INSTRUCTIONS CAREFULLY
& RETAIN THIS COPY FOR FUTURE USE**

WARNINGS

1. WARNING: If You Are Younger Than 18, Do Not Use This Product

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 age 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.

2. 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 have seen 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 lodged 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 and/or varies, i.e., it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

3. WARNING: This Hearing Aid Should Not Cause Pain Upon/During Insertion.

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

please follow the instructions that will appear later in this manual.

4. WARNING: Do Not Use If Any Of The Followings Apply To You

- Congenital atresia of external ear or deformity of any part of the ear canal
- Deafness is unstable, and the degree of hearing loss often fluctuates
- Persistent headaches, dizziness, earaches, tinnitus or other symptoms that are not suitable for adaptation
- Sudden onset of hearing loss within the past 3 months; rapid progressive deafness; unilateral hearing loss or other acute ear disease
- Effusion (secretions/discharge) in the ear and/or frequent purulence (pus).
- Central deafness (central nervous system) or non-organic deafness.
- Patients with acute otitis externa and tympanitis.
- Patients with acute and chronic suppurative otitis media (in the period of purulent infection).
- Patients who are allergic to the materials of this product.

5. WARNING: Important Safety Instruction

- Keep small parts (hearing instrument, ear tips, battery or other detachable parts) that can be swallowed out of children's reach.
- Dropping, immersing in liquid, exposure to strong electromagnetic fields or excessive heat will damage the hearing aid. Remove devices prior to any type of X-ray, MRI, or CT scan.
- If parts become stuck in the ear canal, seek medical assistance-do not attempt to remove by yourself.
- Do not use at high volume for extended periods of time. Ear injury can result.
- If you experience any pain or strong discomfort using the devices, remove and consult a doctor.
- Routine maintenance to keep the device clean is required. Ensure that ear tips are free of debris and moisture at all times.
- Do not store or use the product in environments of high humidity or temperature (such as a sauna or steam room), to avoid damage.
- Batteries should be properly recycled and not disposed in the trash.

- Keep the devices away from children. Injury or damage may result.
- Do not share your hearing aids with others. Using a hearing aid configured for someone else can result in hearing damage or injury.
- Monitor for any unusual skin reaction. If you notice any allergic reaction (itchiness, swelling, or rash), stop wearing the hearing aids and consult a medical specialist.
- Stay away from strong electromagnetic fields when using hearing aid to avoid unexpected damage. Your hearing aids are delicate electronic instruments and may be damaged by contact with strong magnetic equipment such as electromagnetic ovens, microwave ovens, ultrasonic cleaners, etc.
- If the Bluetooth function is available for your device, do not connect the hearing aid and headsets to the mobile phone via Bluetooth simultaneously. Noise, distortion or any other unexpected problems may occur to your hearing aid.
- If needed, please contact the manufacturer for assistance in stepping up, using or maintaining your devices or to report any unexpected operation or events.
- Contact your hearing professional for assistance if needed.
- Do NOT fix your devices by yourself. Doing so will not only void the warranty but also cause further damage easily - Check the "TROUBLESHOOTING GUIDE" first when failures occur to your devices.

CAUTIONS AND NOTICES

1. 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.

2. 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.

3. Caution: You Might Need Medical Help If A Piece Gets Stuck In Your Ear.

If any part of your hearing aid, like the ear tip, 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 farther into your ear, injuring your eardrum or ear canal, possibly seriously.

4. Note: If You Remain Concerned, Consult A Professional.

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

5. 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.

6. Note: Tell The 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.

7.Note:if You Experience Side Effects, Contact A Hearing Care Professional.

Possible side effects from wearing the hearing aid may be:

- Dizziness
- Tinnitus
- Perceived worsening of hearing loss
- Nausea
- Headache
- Skin reaction
- Excessive ear wax accumulation

8.Note:Tips For Better Communication

It will take practice, time, and patience for your brain to adapt to the new sounds that your hearing aids provide. Hearing is only part of how we share thoughts, ideas and feelings.

Reading lips, facial expressions, and gestures can help the learning process and add to what amplification alone may miss.

(1) Please review the following simple communication tips for you:

- Move closer to and look at the speaker.
- Sit face-to-face in a quiet room if possible.
- Try out different locations to find the optimal places to listen.
- Minimize distractions.
- Background noises may be frustrating at first; remember, you have not heard them for a while.
- Let others know what you need; keep in mind that people cannot “see” your hearing loss.
- Develop realistic expectations of what your hearing aids can and cannot do.
- Better hearing with hearing aids are a learned skill combining desire, practice, and patience.

(2) You will learn and adjust, it just takes a little time. Remember to be patient with yourself.

(3) For Your Family and Friends:

Your family and friends are also affected by your hearing loss.

Request that they do the following:

- Get your full attention before beginning to speak.

- Look at you or sit face-to-face.
- Speak clearly and at a normal rate and level; shouting can actually make understanding more difficult.
- Rephrase rather than repeat the same words; different words may be easier to understand.
- Minimize distractions while speaking.

9.Additional Cautions:

- The use of accessories and cables other than those specified by the manufacturer (except for cables sold by manufacturer as replacement parts for internal components) may result in increased emission or decreased immunity of the device.
- Do not use a mobile phone or other devices that emit electro magnetic fields, near the unit. This may result in incorrect operation of the unit.
- Do not bring the device into any MRI, CT, diathermy, RFID and/or electromagnetic security systems such as metal detectors environment or near any of this equipment. Consult manufacturer if you have any questions.
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1) As to devices:

- Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit's essential performance. The device has passed EMC highest interference level test, and the parameters do not deviate the essential performance requirement.
- Abnormality in the display.

2) As to patients:

- The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
- It cannot achieve expected effect.

If this equipment is found to cause or respond to interference,

attempt to correct the problem by one or more of the following measures:

- If feeling too weak or too strong of a stimulation, adjust the strength level to an acceptable level.
- If the device display is abnormal, power off and restart the device and check whether it shows properly.
- Reorient or relocate the affected device.
- Increase the separation between the unit and the affected device.
- Power the equipment from a source other than that of the affected device.
- Consult the service representative for further suggestions.

Getting Started

Remove the product from the box.

Please retain all packaging until you have thoroughly checked and counted all the parts and the contents against the parts list.

Package Contents

Digital Hearing Aid with right hand side ear tube (red “2B” marker installed)

Left hand side ear tube (blue “2B” marker)

Ear Tips x 3 (1pc each for small, medium & large)

Zinc Air A13 Battery x 2

Cleaning Tool

Storage Case

Carrying Pouch

Instruction Manual

Features

Traditional Behind-the-Ear Design

Ergonomic Fit

Active Noise Reduction

Minimal Noise Interference

Two (2) Built-In Microphones for Increased Hearing

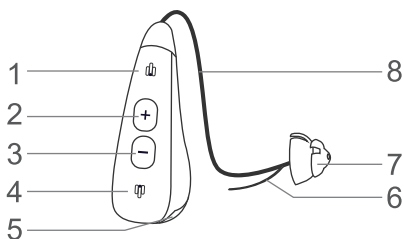
Adjustment Simple +/- Volume Adjustment

Four (4) Program Presents: Standard, Restaurant, Outdoor and Music

Powered by Zinc Air A13 Battery

Replaceable Battery Included

DESCRIPTION OF PARTS



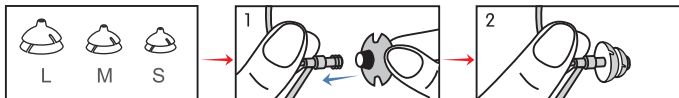
1	Front microphone input
2	Up button +
3	Down button -
4	Rear microphone input
5	Battery compartment
6	Stable line
7	Ear tip
8	Ear tube

INSTRUCTIONS FOR USE

1. Choose and install the ear tips

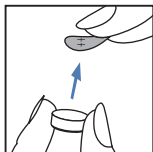
Choose: If the medium size is too tight/loose for you, adjust with the small/large size to see if other is a better fit.

Install: Push the ear tip over the ridges on the thin tube. Make sure it is properly and securely mounted.

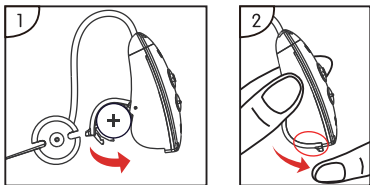


2. Loading of battery

Remove the sticker from a new battery (included) and wait for two or three minutes.



Open the battery compartment. Place the battery in the battery door with the "+" symbol facing upwards.



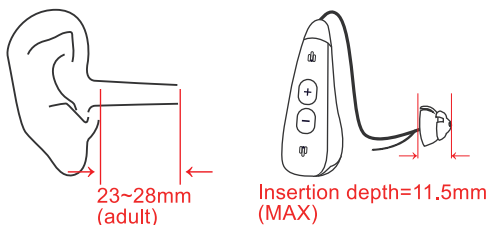
WARNING

This product contains a Button Cell Battery. A swallowed Button Cell Battery can cause internal chemical burns leading to death in as little as two hours. Dispose of used batteries immediately. Keep new and used batteries away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention. Do not mix with used or other types of batteries.

3. Instruction for insertion depth

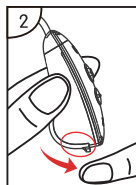
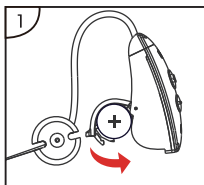
For adults, the average length of the ear canal has been estimated to be 23-28mm and the maximum insertion size of the hearing aid is 11.5mm. So the distance from the ear tip to the tympanic membrane after wearing the hearing aid is at least 11.5mm, which is greater than the lower limit of 10mm specified by OTC.

Therefore, the device is safe and complies with OTC regulations.

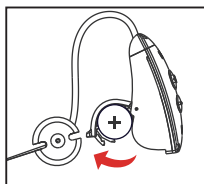


4. ON/OFF the device

To turn ON – Gently open the battery compartment, insert battery, and close the compartment. Then, the device will be set to turn on after a short delay, in order to give you enough time to set it in your ear comfortably before it turns on.



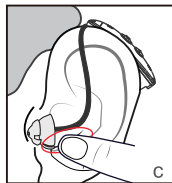
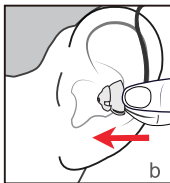
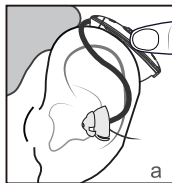
To turn OFF – Simply open the battery compartment a crack. Store it in a safe & dry place.



5. Putting on/off the hearing aid

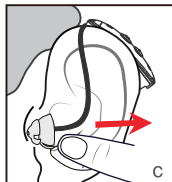
Putting on the hearing aid:

- Place the hearing aid behind your ear.
- Insert the earpiece into your ear canal.
- Tuck the anchor into the bowl of your ear to secure your hearing aid.



Putting off the hearing aid:

Pull on the bend of the tube and remove the hearing aid from behind the ear.



6. Volume control (volume levels & volume memory)

Short press + button once, the volume will increase one level. Short press the – button one once, the volume will decrease one level.

Note:

- You would hear one (1) “beep” sound when the volume is decreased/increased by one level.
- Three (3) “beep” sounds would be heard when the volume reaches maximum or minimum volume level.
- Next time when you use the machine, you don't need to adjust it again because it will memorize your setting.

7. Program switching

Long press the +/- button 3 seconds to change the program.

Note:

There are four (4) programs:

- Normal program: You would hear a single “beep” sound. Restaurant program: You would hear two (2) “beep” sounds. Outdoor program: You would hear three (3) “beep” sounds. Music program: You would hear four (4) “beep” sounds.
- Program memory: The hearing aid will enter Normal program when you use it for the first time. After that, every time you power it back on (from powered off state), the program would be same as your last used preference.

Program	Application situation
Standard program	For quiet environments, such as: home and office.
Restaurant program	For conversation environments, such as: meeting, restaurant.
Outdoor program	For outdoor environments, such as road or supermarket.
Music program	For very noisy environments, such as: bar or crowded places.

8. Maintenance and cleaning

1.To ensure optimal use, it is necessary to regularly clean your hearing aid, ear tube & ear tips from time to time.

- Please use a soft & dry tissue or cloth to clean the hearing aid. Never use chemicals or hard abrasives.
- Please use the provided brush to clean the ear tips with care.
- Please use the provided cleaning tools to clean the ear tube. If it is very dirty, please use a soft & dry tissue or soft cloth for cleaning.

2.It is important to keep your device clean and dry. On a daily basis, clean the hearing aid using a soft cloth or tissue.

3.Clean up earwax adhered to the ear tips by using the thin side of included tool. Remove ear tips from the hearing aid before cleaning and push the ear tips rim membrane outward.

Clean the ear tips with alcohol and dry cloth and wait for the ear tips to dry before attaching them to the hearing aid.

Note:

- We recommend replacing the ear tips every three (3) months.
- If the tips get stiff, brittle, or discolored over time, please change them as soon as possible.

4.In order to avoid damage due to humidity or excessive perspiration, the use of a drying kit is recommended.

5.Operate the controls with care, do not press very hard.

6.If your hearing aid is dropped in water, wipe with dry cloth and allow ample time for it to fully dry before attempting to use or have it tested by Nuvomed Inc.

Troubleshooting

Problem	Possible cause	Solution
Cannot hear sound well	Is the battery exhausted?	Replace with a new battery.
No sound	1.If you turn on the power. 2.If you fit the battery in correct direction. 3.If the battery power has been used up. 4.If the earphone is damaged. 5.If the lead is broken. 6.What to do if the hearing aid was dropped in water? 7.If the hearing aid was accidentally dropped in water or other liquid. 8.Never attempt to dry the hearing aid in a microwave oven, a dish dryer, or with a hair dryer. This may damage the hearing aid.	1.Turn on the device. 2.Remove and re-install the batteries. 3.Replace the new battery. 4.Contact Nuvomed Inc. 5.Contact Nuvomed Inc. 6.Wipe off, then have it tested. 7.Carefully wipe it off with a soft, dry cloth, let it dry and then have it tested by Nuvomed Inc. 8.Compliance with the user manual.
The sound is very weak and vague	1.Battery power isn't enough. 2.If something is wrong with earphone. 3.Is the battery holder closed properly	1.Replace with new batteries. 2.Consult your distributor. 3.Close the battery holder properly

Volume level too high	If the receiver of the hearing aid does not fit the ear properly, or a whistling unpleasant noise may be heard (which is caused by acoustic feedback).	Turn the hearing aid off and reposition it properly in the ear. Or, if the receiver does not fit your ear properly, try replacing it with another type. The use of a correctly fitted ear mold is recommended. Please consult your hearing aid dispenser.
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Specification

Test Standard: ANSI 3.22-2014

Test Equipment: FONIX 8000

Test Coupler: HA-2

The standard test ambient conditions shall be:

Temperature: $23^{\circ}\text{C} \pm 5^{\circ}\text{C}$ ($73^{\circ}\text{F} \pm 9^{\circ}\text{F}$)

Relative humidity: 0% to 80%

Atmospheric pressure: 760 (+37.5,-150) mm of Hg or 101.3 (+5,-20) kPa

1). OTC Hearing aid technical specifications				
Test Items	Program 1	Program 2	Program 3	Program 4
Max. Output (OSPL ₉₀)	110dB	111dB	111dB	110dB
The full-on gain value (HFA FOG@50)	31dB	27dB	33dB	24dB
The total harmonic distortion value (THD)	0.3%	0.5%	0.4%	0.3%
The self-generated noise value (EIN)	21dB	25dB	16dB	20dB
The Latency value	6ms	6ms	6ms	6ms
Frequency response bandwidth	F1=200Hz F2=5600Hz	F1=203Hz F2=5400Hz	F1=210Hz F2=5300Hz	F1=200Hz F2=7500Hz
Frequency response smoothness	6dB	7dB	8dB	6dB

2). Battery life
The battery life of a hearing aid is up to 235 hours.

- The data is derived from values measured in a laboratory. The values may vary during real life application of the product.

Normalized symbols

	Follow operating instructions
	B type applied part
	Needs protection from moisture
	Manufacturing date
	Manufacturer information
	Batch code
	Serial number
	USE BY
	Warning/ Danger: Improper use might cause serious injuries.
	Medical Device
Storage/Transport 	Permissible storage and transport temperature and humidity
Operating 	Permissible operating temperature and humidity

Maintenance, storage, and disposal

- Maintenance
 - 1) We do not authorize any institution or individual to maintain and/or repair the product. If you suspect that the products may be in question, please contact us immediately.

- 2) The user must not attempt any repairs to the device or any of its accessories. Please contact us for any repair needs.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty. Warning : No modification of this equipment is permitted.

- **Storage**

- 1) Always store your rechargeable devices in the Charging Case when not in use.
- 2) Do not store or expose the devices and/or case to extreme hot/cold temperatures, moist/humid environments, or shock/vibration.
- 3) Keep the devices and case in following environmental ranges:-10°C ~55°C, 10%-90%RH, 700-1060hPa
- 4) The hearing aids should be fully charged before used for the first time. The hearing aids should be charged at least every six (6) months if they are not used for an extended period of time.

Warranty

WARRANTY DURATION: All materials and workmanship are warranted to the original consumer and purchaser for a period of ninety (90) days from the original date of purchase. Proof of purchase required to ensure warranty coverage.

WARRANTY COVERAGE: This product is warranted against defective materials or workmanship. This warranty is void if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, repairs by unauthorized personnel or other causes not arising out of defects in materials or workmanship. This warranty is effective only if the product is purchased and operated in USA and does not extend to any units which have been used in violation of written instructions furnished by Nuvomed Inc. or to units which have been altered or modified or, to damaged products or parts thereof which have had the serial number removed, altered, defaced or rendered illegible.

WARRANTY DISCLAIMERS: This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for Nuvomed Inc. any other liability in connection with the sale of our products. There shall be no claims for defects or failure under

any theory of tort, contract or commercial law including but not limited to, negligence, gross negligence, strict liability, breach of warranty and breach of contract. Under no circumstances will Nuvomed Inc.'s / Distributor's maximum liability exceeds the retail value of the product.

WARRANTY PERFORMANCE: During the above 90 days warranty period, a product with a defect will be either repaired or replaced with a reconditioned comparable model (at Nuvomed Inc.'s option). The repaired or replacement product will be in warranty for the balance of the 90 days warranty period and an additional one-month period. No charge will be applicable for such repair or replacement.

SERVICE AND REPAIR: If service is required for this product, you should first contact Nuvomed Inc. Customer Service at info@nuvomed-hearingaids.com or by calling 1-888-738-NUVO (1-888-738-6886), Monday to Friday 10am to 6pm EST.

NOTE: Nuvomed Inc. cannot assume responsibility for loss or damage during shipment. As a precautionary measure, carefully package the product for shipment, and insure it with the carrier. Be sure to enclose the following details with the product: your full name, return address and daytime phone number, a note describing the problem you experienced, a copy of your sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

Nuvomed Inc.'s return policy:

To return this device, please call our customer care team at 1-888-738-NUVO (1-888-738-6886) or email us at support@nuvomed-hearingaids.com. We shall work to ensure that your return is processed smoothly, and you receive your credit in a timely manner. *Returns maybe subject to a restocking fee and return shipping costs.

Distributed by NuvoMed, Inc, Downers Grove, IL 60515

Product Life: 5 years

