

物料编号：1.4.05.A17BT.002

客户型号：HSA-4/0142

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-A17BT 定制OTC英文说明书		
	文件编号：W100-C-A17BT-20230201-01 版本号：V0		
	○ 订单号：22PI432		
	制作：Victor	需求：Maggie	核准
	制作日期：2023年02月01日		



NuvōMed®

**DigiEars | MAX
Complete In-Canal
Hearing Aid with Charging Case**

Model: HSA-4/0142



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 This Product If Any of the Following 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(s), ear tips, battery or other detachable parts) that can be swallowed out of reach of children.
- Dropping, immersing in liquid, exposure to strong electromagnetic fields and/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 the device 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 them immediately and consult a doctor.
- Routine maintenance to keep the device clean is required. Ensure that the 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 of 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 the hearing aids 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 a wireless headset to the mobile phone via Bluetooth simultaneously. Noise, distortion or any other unexpected defect may occur to your hearing aid and result in the forfeiture of the warranty on your device.
- If needed, please contact the manufacturer for assistance in setting 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 - Check the "TROUBLE-SHOOTING 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

Ear Tips x 3 pairs (2pcs each for small, medium & large)

Charging Case

USB Cable

Cleaning Tool

Carrying Pouch

Instruction Manual

Features

Discreet CIC Design

Easily Adjustable Single Key Volume Control

Active Noise Reduction

Minimal Noise Interference

Digital 4 channel DSP Chip

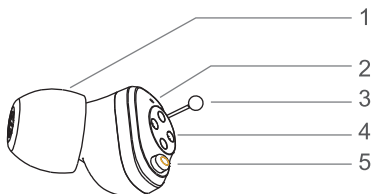
4 Programmed presets: Standard, Restaurant, Outdoor and Music

Charging time (Case): 2.5hr

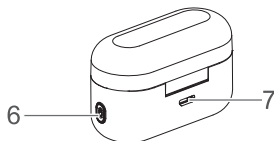
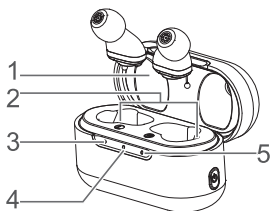
Working time: $\geq 12\text{hr} \times 3 \text{ times} = 36$

Full Charge Case Carries 2 Full Recharges for Up To 36 Hrs of Usage

DESCRIPTION OF PARTS



1	Ear tip
2	Microphone
3	Pull string
4	Charging contacts
5	Multi-function button



1	Upper cover
2	Charging slots
3	Charging indicator of hearing aid (L)
4	Charging indicator of charging case
5	Charging indicator of hearing aid (R)
6	Battery check button
7	Charging port

INSTRUCTIONS FOR USE

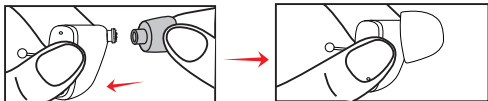
1. Choose and install the ear tips

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

b: Push the ear tips rim membrane outward.



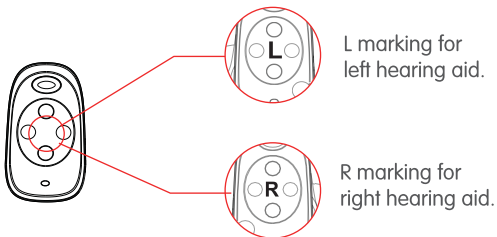
c: Hold on to the end of the hearing aid and push firmly to ensure that the hook and tips are fastened securely.



Note: Please pull the tips gently to check if it is firmly attached and ensure the tips won't fall off easily.

2. Left & right hearing aid markings

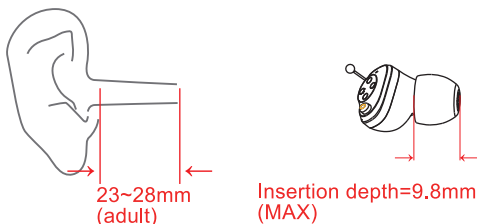
There is a L or R marking on the hearing aid. The L marking is for the left hearing aid, and the R marking is for the right hearing aid.



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 9.8mm. So the distance from the eartip to the tympanic membrane after wearing the hearing aid is at least 13.2mm, which is greater than the lower limit of 10mm specified by OTC.

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

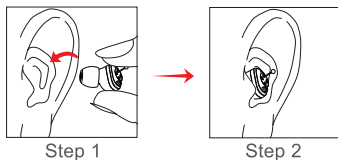


4. Wearing & removing hearing aid

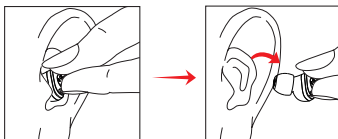
Wearing:

Step 1: Hold the hearing aid and place it in your right or left ear.

Step 2: Move the hearing aid slightly into auricle for holding.



Removing: Grasp the protruding hearing aid and remove it from your auricle gently.



Note:

- The creak sound can be used as a reference to determine whether the hearing aid is secured.
- If the hearing aid gives out squeaking, please check if it is inserted correctly. If correctly inserted and the squeaking remains, please replace with the other size of the ear tip. When the hearing aid is not in use, please turn it off without delay.
- When the hearing aid is not functioning properly, please check the "TROUBLESHOOTING" guide and if none of the solutions work, please contact the Nuvomed Inc. Expert Care Team.

5. Turning on/off the hearing aids

Turning on the hearing aid:

Turn on your hearing aids by pressing the multi-function button for about six (6) seconds. You will hear a prompt tone according to the hearing program (refer to "HEARING PROGRAM CHANGE")

Turning off the hearing aids:

- Turn off your hearing aid by pressing the multi-function button for about 6 seconds. You will hear three (3) beeps.
- You will hear the prompt tone of program-changing when you try to turn your hearing aid off. Keep pressing until you hear the turn-off prompt tone.



6. Volume adjustment

- The hearing aid has six (6) volume levels.
- You could adjust the volume from minimum to maximum by short pressing the multi-function button.
- The hearing aid will give out the prompt tone of three (3) beeps at maximum volume.



7. Hearing program change

- There are four (4) pre-set programs in the hearing aid.
- You could change the hearing program by long pressing the multi-function button for about three (3) seconds.
- The hearing aid is designed with memory function: The hearing aid can record the previous hearing program automatically.
- Your hearing aid beeps to indicate which hearing program you are in.

Hearing program		Prompt tone
1	Standard	One (1) Beep
2	Restaurant	Two (2) Beeps
3	Outdoor	Three (3) Beeps
4	Music	Four (4) Beeps

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. Charging the hearing aid

- When the hearing aids are turned off and placed back into the correct slot of the charging case, they will start charging.
- The orange indicator light indicates that the hearing aid is properly charging, and the green indicator light indicates that the hearing aid is fully charged.
- The indicator lights of the hearing aid will go out about five (5) minutes after the hearing aids are fully charged.
- Low battery warning: You will hear the notification sound when the remaining battery capacity is at a critical level.

9. Charging case

- The charging case will charge the hearing aid whenever the upper cover is opened or closed. The charging process will stop automatically when the case and hearing aids are fully charged.
- Check the “TROUBLESHOOTING” when charging or other failure occurs to your devices.

a.Turn on/off

Turn on – You can turn on the charging case by pressing and holding the battery check button for about two (2) seconds. Every indicator light of the charging case will turn green and flash three (3) times.

Turn off – Press and hold the battery check button for about five (5) seconds to turn off the charging case. Every indicator light of charging case will turn orange and flash three (3) times.

b.How to charge the charging case

Connect the included USB cable to the charging port of the charging case and attach the other end of the cable to your computer USB port or any other USB enabled power source.

c.Battery power check

Short press the battery check button to check the remaining battery capacity of charging case and hearing aid.

Charging case is NOT connected to the USB power source

- The solid green indicator lights indicate that the remaining battery capacity is full.
- The flashing orange indicator lights indicate that the remaining battery capacity is NOT full.

Charging case is connected to the USB power source

- The solid green indicator lights indicate that the remaining battery capacity is full.

The solid orange indicator lights indicate that the remaining battery capacity is NOT full.

Maintenance and cleaning

1.Hearing Aid care

- Keep your hearing aid clean. Extreme temperature (heat or cold), moisture, and foreign substance can result in poor performance.
- Use the included cleaning tool to clean debris that may collect on the buttons, microphones, and charging contact; inspect the receiver, ear tips, and charging case regularly.
- DO NOT clean your hearing aid with water, solvent, cleaning fluids

or oils.

- Charging contacts should always be kept clean and dry.
- Always store your hearing aid in the charging case when not in use.

2.Charging case care

- Keep your charging case clean. Extreme temperature (heat or cold), moisture, and foreign substances can result in poor performance.
- Use the included cleaning brush to keep the charging ports clear of debris at all times.
- DO NOT use water, solvents or cleaning fluids or oils to clean the charging ports.
- Store your charging case in a clean and dry location.

3.Care and maintenance

- Keep your device away from children and pets.
- Keep your hearing aid away from high-temperature and/or high humidity environments.
- Do not poke the microphone with any sharp objects to avoid damage.
- Do not attempt to disassemble or repair your devices by yourself. Doing so will void your warranty and cause further damage.
- Clean the charging contact of the rechargeable hearing aid with dry and soft cloth regularly to ensure the normal charging.

4.Cleaning

- Clean earwax that collects on the ear tips by using the thin side of the included tool.
- Remove ear tips from the hearing aid before cleaning and push the ear tip rim membrane outward.
- Clean the ear tips with alcohol and a 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 3 months.
- If the tips get stiff, brittle, or discoloured over time, please change them as soon as possible.

5.Cleaning tool

Use a soft cloth or tissue to wipe any moisture or perspiration from the surface of the cleaning tool.

Troubleshooting

Problem	Possible cause	Solution
Feedback or "whistling"	1.Is the hearing aid inserted correctly in your ears? 2.Is the volume too loud? 3.Are the ear tips broken or clogged? 4.Are you holding an object (e.g. a hat or a telephone mouthpiece) close to the hearing aid? 5.Is your ear full of wax?	1.Reinsert the hearing aid in your ears. 2.Reduce the volume. 3.Replace the ear tips. 4.Move your hand away to create more space between the hearing aid and the object. 5.Visit your physician.
No sound	1.Are the hearing aids charged? 2.Is the charging case charged? 3.Is your ear full of wax?	1.Charge the hearing aids. 2.Charge the charging case. 3.Visit your physician.
Hearing aid is not charging	1.Are the hearing aids sitting correctly in the charging case? 2.Is the charging case charged or plugged into a USB power source?	1.Reinsert the hearing aids in the charging case. 2.Charge the charging case.
Indicator light of hearing aid does not light up when hearing aid placed in charging case	1.Poor contact between hearing aid and charging case. 2.Hearing aid is not inserted correctly into charging case. 3.Charging case is not connected to USB power source. 4.Are the hearing aids charged? 5.Dirty charging contacts.	1.Reinsert the hearing aid into the charging case. 2.Insert hearing aid correctly into charging case. 3.Connect charging case to external USB power source. 4.Charge the hearing aids. 5.Clean the contact of the hearing aid and charging case.

Charging does not start	Hearing aid is not inserted correctly into charging case.	Insert hearing aid correctly into charging case.
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Specification

Test Standard: ANSI 3.22-2014

Test Equipment: FONIX 8000

Test Coupler: HA-1

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 aids technical specifications				
Test Items	Program 1	Program 2	Program 3	Program 4
Max. Output (OSPL ₉₀)	106dB	104dB	107dB	102dB
The full-on gain value (HFA FOG@50)	24dB	24dB	25dB	21dB
The total harmonic distortion value (THD)	0.4%	0.2%	0.3%	0.2%
The self-generated noise value (EIN)	16dB	16dB	14dB	17dB
The Latency value	14ms	14ms	14ms	14ms
Frequency response bandwidth	F1=220Hz F2=5100Hz	F1=240Hz F2=5300Hz	F1=220Hz F2=5200Hz	F1=200Hz F2=6300Hz
Frequency response smoothness	3dB	5dB	4dB	3dB

2). Battery life & Discharge time of the charging case	
Test Items	Value
Battery life of hearing aids	12h
A pair of hearing aids charging times with fully charging case	2 times

● 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