KINETIK WELLBEING
HEARING AMPLIFIER
USER MANUAL



Please read instructions carefully before operating this device.

Thank you for buying the Kinetik Wellbeing Hearing Amplifier.
This device will enhance your hearing both indoors and outdoors.
Please read instructions carefully before use.

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I. INTRODUCTION

1.1What is hearing loss?
A speech frequency puretone average (average of hearing thresholds at 0.5, 1, 2 and 4 kHz) or greater than 25 dB hearing level (HL) in both ears was defined as hearing loss as per the World Health Organization criteria, and this is the level at which hearing loss begins to impair communication in daily life. (Extracted from the literature of: World Health Organization prevention of Blindness and deafness (PBD) program. Prevention of Deafness and Hearing-Impaired Grades of Hearing Impairment)

1.2 What's the hearing amplifier?
The Kinetik Wellbeing hearing amplifier is a wearable, sound-amplifying air-conduction aid. The fundamental principle of the hearing amplifier is to receive, amplify and transfer sound to the ear drum of the user.

II. INTENDED USE

2.1 Medical purpose
The hearing amplifier is intended to assist those with impaired hearing.

2.2 Intended patients and environment
The hearing amplifier can be used indoors and outdoors.

If a doctor has decided that you require a hearing amplifier - patients must be over 36 months old.

2.3 Side effects
- Patients sensitive to silicone may experience ear canal pruritus.
- First use may cause slight pain as the ear canal adjusts to the hearing amplifier.

III. IMPORTANT SAFETY INSTRUCTIONS

Read all the information in the instruction manual and any other literature included in the box before using the device.

3.1 CONTRAINDICATION ⚠WARNING
The device is unsuitable and should not be used in the following situations:
- Patients with chronic suppurative otitis media, congenital ear atresia;
- This hearing amplifier can only be used to assist patients with hearing impairment, there is no therapeutic value.
- The hearing amplifier cannot be used by infants under 36 months old.

3.2 WARNINGS ⚠WARNING
- Keep small parts (hearing instrument, battery and detachable parts) that can be swallowed out of children' s reach. Dropping, immersing in liquid, strong electromagnetic fields or excessive heat will damage the hearing amplifier. If parts remain in the ear, please go to see a doctor as soon as possible, do not take it out by yourself.
- Remove the battery if it is not likely to be used for some time – this is to avoid battery leakage.
- Remove the sealing on the positive side of battery before loading. The battery operates normally in about 1 minute after the sealing is removed.

- Open the battery compartment lid. Load a battery into the battery compartment with correct polarity, the plus mark＋on the battery and the lid should be on the same side. Otherwise, the hearing amplifier will not work properly.
- Close the battery compartment lid. Dispose of batteries and the hearing amplifier following battery recycling management protocol. Do not throw into fire, as the battery may explode.
- Always store batteries out of reach of children, to avoid accidental swallowing.

3.3 Notice
- Don' t use device at high volume for a long time - otherwise it may injure your ear. If you feel uncomfortable, please stop using.
Please maintain the products at all times. Prevent the earplug and acoustic opening from becoming obstructed with foreign matter. This impairs the function of sound amplification.
- Protect the device from impacts, humidity and high temperatures.

Don' t throw the scrapped battery as common rubbish, it should be handled with specialist equipment, to avoid environmental pollution.
- Do not use this product near explosive or dangerous environments, to avoid damaging the hearing amplifier.
- Keep device away from children as there is a risk of injury to the child or others, or damage to the device.
- Don' t use in an oxygen rich environment for long periods as this may damage the device.
- Do not set volume levels too high. Listening for extended periods at high volume levels can cause further hearing damage. Special care must be taken because this hearing amplifier is a high-output type.
- Do not lend your hearing amplifier to other persons. Using a hearing amplifier designed for someone else can result in hearing damage.
- Monitor any unusual skin reaction. In some instances, wearing a hearing amplifier can cause an allergic reaction leading to itchiness or rashes. If you notice any unusual skin condition, stop wearing the hearing amplifier and see a medical specialist.
- Do not put a magnetic item into contact with the hearing amplifier as this may damage the device.

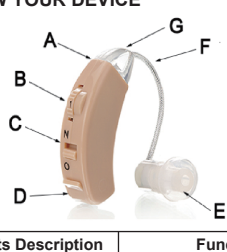
- Be sure to take off the hearing amplifier when getting a diagnosis or treatment regarding your hearing (If you get them with hearing amplifier worn, ensure that the hearing amplifier is not activated.)
- Do not touch the interior of the hearing amplifier as it contains many delicate parts that are precision adjusted. Never pry the inside of the hearing amplifier with a needle or similar object, otherwise it will damage the device.
- Do not place in a hot or humid location. You should never leave your hearing amplifier near heating appliances or in direct sunlight, and you should also avoid humid locations such as bathrooms or near a humidifier. Otherwise it will damage the device.
- In a closed car in summer, the temperature can rise to very high levels. Do not leave your hearing amplifier in a car, otherwise it may damage the device.
- Do not use the hearing amplifier together with a mobile phone, otherwise it may increase the noise and affect the sound quality.
- Radio wave emissions from mobile phones can cause noise in the hearing amplifier or result in reduced volume.

- Please contact Kinetik Wellbeing for assistance:
• in setting up, using or maintaining the hearing amplifier; or
• to report unexpected operation or events.

Specific warnings

Specific warnings / statements
Keep small parts out of children´s reach, to avoid them swallowing parts
Warning - Common conditions that can damage the device
Warnings that result from the risk management file
Permissible environmental conditions of transport and storage
Each warning/safety contains: nature of Hazard, likely consequence; precautions.
Statement about the special needs of particular Patient groups

IV. KNOW YOUR DEVICE



NO.	Parts Description	Function
A	Microphone	/
B	Volume control	"1~4" Volume grade, "1"Min, "4"Max
C	On/Off switch	"N" means "Power On" "O" means "Power Off"
D	Battery compartment	"+" Positive electrode of Battery "-" Negative electrode of Battery
E	Ear plug	/
F	Headphones	/
G	Ear Tube	/

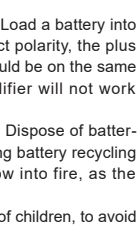
List of accessories

Part name	Type and specification	QTY	Part no.
Battery	LR754 battery D.C. 1.4V (JH-125: d.c. 1.5V)	1pc	030-700501-542
Earplug	Silicone gel	3pcs	031-010000-001

NOTE: Always use the original accessories from Kinetik Wellbeing. Changing or replacing the accessories without consulting Kinetik may be unsafe and reduce effectiveness of the device.

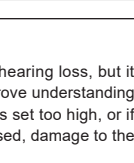
V. HOW TO USE

Turn on the device
1)Before use, make sure the power is off, or set the volume to "1".
2)When the battery compartment is closed, put amplifier on the ear and switch the "O-N switch" to N position to turn on the device

Inserting/Replacing the battery

1)When the sound is weak, this may indicate that the battery is low and needs to be replaced.
2)Open the battery door completely. Remove the used battery if present.
3)Prepare the new battery. Insert the new battery with the positive side in the correct position.
4)Gently close the battery door.

Initial use and operation
1)Connect the earplug on the amplifier tightly.
2)Put the ear hook on your ear, plug in the ear plug tightly.
(Note: The unit is on "off" position. And volume is on "1" , otherwise the instant sound may be uncomfortable).
3) Adjust the sound volume to get clear sound.
4) If you hear a whistling sound, please check whether you have inserted the ear plug correctly into the ear canal. If it can't insert deeply, please change to another silicone tip.

5) A hearing amplifier cannot cure hearing loss, but it can augment your hearing and improve understanding of speech. However, if the volume is set too high, or if an unsuitable hearing amplifier is used, damage to the ear may occur.
6) Before using a hearing amplifier, be sure to have your hearing tested at a medical facility or by a qualified hearing amplifier dispenser. Hearing amplifier adjustment should only be carried out by a trained professional, such as an otolaryngologist, audiologist, or qualified staff at a hearing amplifier dispensary.
7) Keep the volume level low at first, and then gradually increase it as you get used to the hearing amplifier.
8) The hearing amplifier is adjusted for your individual requirements. It will not fit and may cause hearing damage and infection when worn by other persons. Do not lend your hearing amplifier to others, and do not use a hearing amplifier belonging to someone else.



Note:
-Hearing problems in children are especially difficult to diagnose. Children should only be fitted with a hearing amplifier under the supervision of an otolaryngologist.
- If you currently have an ear ailment or have had an ailment in the past, consult your physician before using a hearing amplifier.
- You should never attempt to bend or modify the shape of the thin tube.

Removal
1）Hold the thin tube with your thumb and forefinger.
2） Then remove the ear hook from your ear. If any part of the hearing amplifier remains in the ear consult a professional immediately.
3） Consult your hearing care professional if you have difficulties removing the hearing amplifier.

Stop using the Hearing Amplifier
1) If any of the symptoms described below occur, stop using the hearing amplifier and seek medical assistance or contact your hearing amplifier dispenser:



-- There is a rash or eczema where the hearing amplifier has contact with skin.
-- The parts of the hearing amplifier that come into contact with skin are made of a special material designed to minimize skin irritation. However, in rare cases, allergic reactions may occur, which can lead to eczema.
-- There is discharge from the ear during hearing amplifier use, or treatment of the ear has become necessary.
-- Hearing capability has suddenly deteriorated markedly.

VI. MAINTENANCE AND CLEANING

6.1Daily maintenance

It is important to keep your instrument clean and dry. On a daily basis, clean the hearing instruments using a soft cloth or tissue. In order to avoid damage due to humidity or excessive perspiration, the use of a drying kit is recommended.

6.2Care and maintenance
■ Put it out of reach from children, keep dry and do not expose in the sun.
■ Do not expose the hearing amplifier to heat from stoves, etc. Also, avoid leaving it in places with high humidity.
■ Operate the controls with care. Do not press hard.
■ If the hearing amplifier is dropped in water, wipe with dry cloth and contact manufacturer.
■ Do not pick the microphone with nail, pin, etc. As this will cause the microphone to be damaged.
■ Do not disassemble or attempt any repairs by yourself. Contact Kinetik Wellbeing for assistance.

6.3Cleaning
1)Cleaning the earplug

Remove ear wax in the earpiece using a cotton bud.

2)Cleaning hook
■ Using a soft cloth or tissue wipe off any moisture, perspiration, or debris from the surface of the hook.
Note: Do not use alcohol or other cleaning solvents to clean the hook as this could damage the protective covering.

VII. TROUBLESHOOTING

Check the following if the device should fail during operation.

Problem	Cause	Remedy
No sound	1). Power is off. 2). Battery is incorre -ctly fitted. 3). Battery is flat. 4). Earphone is dama -ged. 5). Lead is broken 6). Hearing amplifier is dropped in water or other liquid. 7). Hearing amplifier was in a microwave oven, a dish dryer, or used with a hair dryer. This may damage the hearing amplifier.	1) Turn on the devices; 2) Remove and re -install the battery; 3) Replace the new battery; 4/5) Contact Kinetik Wellbeing or distributor; 6) Carefully wipe it off with a soft, dry cloth. Then have it tested by your hearing amplifier dispenser as soon as possible. 7) Please ensure total compliance with manual.

Problem	Cause	Remedy
The sound is very weak and vague	1). Battery power is weak. 2). Damage or fault to earphone. 3). Receiver or tube is clogged with earwax. 4). Battery compart -ment is not properly closed. 5). Tube is blocked by water droplets.	1）Replace the new battery; 2）Contact your distri -butor; 3）Remove the receiver and tube from the hearing amplifier and carefully wash these parts with lukewarm water or similar. 4）Close the battery compartment correctly. 5）Remove the tube and shake it or blow through it to remove the water.
Volume level set too high	Receiver of the hearing amplifier does not fit the ear properly, or a whistl -ing unpleasant noise is heard (which is caused by acoustic feedback).	1)Turn the hearing amplifier off and reposition it properly in the ear. If the receiver does not fit your ear properly, try replacing it with another type. The use of a correctly fitted ear mold is recommend. Please consult your hearing amplifier dispenser.

Problem	Cause	Remedy
Cannot hear sound well	1)Battery is flat 2) The receiver or tube is clogged with earwax	1) Replace with a new battery. 2) Remove the receiver and tube from the hearing amplifier and carefully wash these parts with lukewarm water or similar.

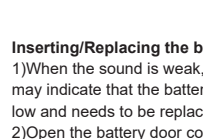
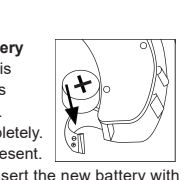
VIII. SPECIFCATIONS AND TYPE

Device name	Hearing Amplifier
Mode	JH-125
Type	BTE
Power supply	DC 1.5V, LR754 button battery (JH-115: DC1.5V)
Working current	≤10mA 1.5V
Sound travels mode	Gas conductivity
Signal process -ing method	Analog signal amplification
Max sound output (Peak OSPL90)	≤ 133+3dB

Sound gain (HFA Full-on gain，50 dB SPL input)	≤42+3db
Sound pressure level (HFA OSPL90)	126.8±3dB
Total harmonic distortion	≤10% 1600Hz
Frequency range	900-3500Hz
Input noise（EQ input noise）	≤ 45dB
Material of shell	ABS
Material of hook	PVC
Material of ear plug	Silicone gel
Type of protection against electric shock	Internally power supply
Degree of protec -tion against electric shock	Continuous operation

Grade of waterproof	IP41
Product life	3 years
Sterilized?	No
Used in an Oxygen Rich Environment	No
Software version	V1.0
Operation environment	-10~40℃, 30%~75%RH, 860-1060hPa
Storage & transportation environment	-10 ~+50 ℃, ≤90%RH, 700-1060hPa

*The above specifications are subject to change without prior notice.Result of Maximum output (OSPL 90) Result of Full-on and reference test gain

1）Measured by Huizhou JINGHAO medical technology Co., Ltd.
2) The test result was according to IEC 60118-7:2005.

Notes:
-This hearing amplifier is produced under the strict quality system of Huizhou JINGHAO medical technology Co., Ltd.
-The device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the Harmonize Standard as IEC 60601-1, IEC 60601-2-66, IEC 60118-7, IEC 60118-13, EN ISO 10993-1/-5/-10 and EN ISO 14971.

IX. EXPLANATION OF SYMBOLS

	Follow operating instructions
	B type applied part
	Disposal in accordance with Directive 2002/96/EC (WEEE)
CE 1639	Complies with the European Medical Device Directive (93/42/EEC and amended Directive 2007/47/EC. Notified Body is SGS Belgium.
	Manufacturer information: The manufacturer is: Huizhou JINGHAO medical technology Co., Ltd.
EC REP	Authorized representative in the European Community. The European representative is: Shanghai International Holding Corp
	Date of manufacture
SN	Serial number
	Warning/ Danger: Improper use might cause serious injuries.

IP41	IP code of the device: this device's grade of against ingress of solid foreign objects – the access probe of 2.5 mm Ø shall not penetrate; the grade of waterproof is v ertically falling drops shall have no harmful effects.

X. MAINTENANCE, STORAGE AND DISPOSAL

10.1 Maintenance
1)We do not authorise any institution or individual to maintain and repair the product. If you have any questions, please contact the manufacturer or distributor.
2)The user must not attempt any repairs to the device or any of its accessories. Please contact the manufacturer for repair.
3)Opening of the equipment by unauthorised agencies is not allowed and will terminate any claim to warranty.
warning: No modification of this equipment is allowed!

10.2 Storage
1)If you don' t use it, turn off the hearing amplifier, take out the batteries, and then put it into the travel case.

2)Don' t put the device directly in the sun, high temperature and moist environments or where it is vulnerable to fire or vibrations.
3)Keep the device storage in following environmental ranges:
-10~50℃, ≤90%RH, 700-1060hPa

10.3 Disposal
Please dispose of the device in accordance with the directive 2002/96/EC – WEEE (Waste Electrical and Electronic Equipment). If you have any queries, please refer to the local authorities responsible for waste disposal.

XI.GUARANTEE

Any damage caused by improper handling shall not be covered by the guarantee. User damaged packaging are also excluded from the guarantee. All other damage claims excluded. A guarantee claim must be submitted with the purchase receipt. Please pack your defective instrument well and send with tracked postage to Kinetik Wellbeing.

Huizhou Jinghao Medical Techology Co., Ltd.
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EC REP Shanghai International Holding Corp.GmbH(Europe)
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