# **KINETIK WELLBEING** HEARING AMPLIFIER **USER MANUAL**



se read instructions carefully before operating this device.

ank you for buying the Kinetik Wellbeing Hearing Amplifier. device will enhance your hearing both indoors and outdoors. This devic 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 AWARNING

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 A 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

Open the battery compartment lid. Load a battery into the battery compartment with correct polarity, the plus  $\mathsf{mark} + \mathsf{on}$  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



<ul> <li>Remove the battery if it is not likely to be used for some time – this is to avoid battery leakage.</li> <li>Remove the sealing on the positive side of battery before loading. The battery operates normally in about 1 minute after the sealing is removed.</li> </ul>					ification. tect the device from eratures.	impacts, humidity and high
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Kinetik Wellbeing. Changing or replacing the accesso ries 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

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 otolarvngologist, 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.



#### 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. Then remove the ear hook from your ear. If any part 2) 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:

#### 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.

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





Put it out of reach from children, keep dry and do not

Do not expose the hearing amplifier to heat from

stoves, etc. Also, avoid leaving it in places with high

If the hearing amplifier is dropped in water, wipe with

Do not pick the microphone with nail, pin, etc. As this

Operate the controls with care. Do not press hard.

yourself. Contact Kinetik Wellbeing for assistance.

6.2Care and maintenance

dry cloth and contact manufacturer.

will cause the microphone to be damaged. Do not disassemble or attempt any repairs by

expose in the sun.

humidity.

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 exce ve perspi ration, the use of a drying kit is recommended.



# VII. TROUBLESHOOTING

Check the following if the device should fa operation.

			weak anu	[2). Damaye
Problem	Cause	Remedy	vague	earphone. 3). Receive
No sound	<ol> <li>Power is off.</li> <li>Battery is incorre- ctly fitted.</li> <li>Battery is flat.</li> <li>Earphone is dama- ged.</li> <li>Lead is broken</li> <li>Hearing amplifier is dropped in water or other liquid.</li> <li>Hearing amplifier</li> </ol>	<ul><li>4/5) Contact Kinetik</li><li>Wellbeing or distributor;</li><li>6) Carefully wipe it off</li></ul>		<ul> <li>a) A closed wit</li> <li>b) A strength</li> <li>c) A strength</li> <li li="" strength<=""> <li li="" strength<=""> <l< td=""></l<></li></li></ul>
	was in a microwave oven, a dish dryer, or used with a hair dryer. This may damage the hearing amplifier.	dispenser as soon as possible. 7) Please ensure total	Volume level set too high	Receiver or hearing am does not fit properly, or -ing unplea is heard (w caused by



using a cotton bud. 2)Cleaning hook

1)Cleaning the earplug

Remove ear wax in the earpiece

6.3Cleaning

 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.



	Problem	Cause	Remedy
ail during	is very weak and	<ol> <li>Battery power is weak.</li> <li>Damage or fault to</li> </ol>	1)Replace the new battery; 2)Contact your distri
Remedy	vague	earphone.	-butor; 3)Remove the receiver
vemedy we and re ve and re ve battery; ce the new tact Kinetik g or distributor; ully wipe it off f, dry cloth. ve it tested by ring amplifier r as soon as e ensure total ace with		<ol> <li>Received or tube is clogged with earwax.</li> <li>Battery compart -ment is not properly closed.</li> <li>Tube is blocked by water droplets.</li> </ol>	and tube from the hearing amplifier and carefully wash these parts with lukewarm
	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.
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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.

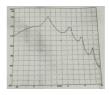
# VIII. SPECIFCATIONS AND TYPE

Device name	Hearing Amplifier		
Mode	JH-125		
Туре	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		
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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

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	300-4000Hz
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







1)Measured by Huizhou JINGHAO medical technology

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

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

<b>(</b>	Follow operating instructions
Ŕ	BF type applied part
X	Disposal in accordance with Directive 2002/96/EC (WEEE)
<b>C €</b> <sub>1639</sub>	Complies with the European Medical Device Directive (93/42/EEC and amended Directive 2007/47/EC. Notified Body is SGS United Kingdom Ltd.
	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
$\triangle$	Warning/ Danger: Improper use might cause serious injuries.

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 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.

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Huizhou Jinghao Medical Techology Co., Ltd. Address: Floor 6, Huicheng Industry Building, No.9 HuifengDong'er Road, Zhongkai High-tech Zone, Huizhou City, Guangdong Province, China.	
EC REP Shanghai International Holding Corp.GmbH(Europe) Eiffestrasse 80, 20537 Hamburg, Germany	
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JH 125 <125±3dB

Full on gain (input 50 dB SPL)

Reference test setting(RTS)

FrequencyRange (Hz) 100

Equivalent Input Noise atRTS (dB SPL)

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

1)We do not authorise any institution or individual to

maintain and repair the product. If you have any ques-

2)The user must not attempt any repairs to the device or

any of its accessories. Please contact the manufacturer

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

**10.2 Storage**1)If you don't use it, turn off the hearing amplifier, take

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out the batteries, and then put it into the travel case.

tions, please contact the manufacturer or distributor.

IP41

for repair.

allowed!

10.1 Maintenance

Total Harmonic Distortion at 500Hz/800Hz /1600Hz (%)

Reference test Gain (dB) ≤ 32dB Current Drainat RTS (mA) <10mA Typical Battery Life (h)

126.8±3dB

JH-125

40±5dB

JH-125

120H

≤ 32dB

≤10%

~6000Hz

35dB±5dB

Performance Characteristics according to IEC 60118-0: 2015 OSPL90 Model

Maximum (dB SPL) HFA- OSI (dB SPL) OSPL90

Model

Model

Maximum (dB)

FA- FOG(dB)