


CERTIFICATE	
Product Name	Hearing Aid
Product Life	5 years
Model	JH-DW3F
Lot No.	Outside packaging
Inspector	
The product conforms to the national and industrial standards and has passed inspection.	



VER: DW3F-20240129-V2

OTC

HEALTHCARE

OXILINE

# Hear XS Pro

HEARING AID ♦ MODEL: JH-DW3F



Please read this user manual thoroughly and completely before using the product.  
This product should be used under the guidance of professionals.

## WARNINGS

### **1.WARNING:If you are younger than 18,do not use this.**

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 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 saw 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

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: 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 when inserting it.**

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

**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, eartips, 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 eartips 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 sauna 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.

● Please contact the MANUFACTURER:

For assistance, if needed, 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 easily - Check the "7.1 Troubleshooting" 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 eartip, 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 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:

- 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 manufacturer, with the exception of 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 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 and that 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.
- The device displays abnormally.

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 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.
- Re-orient or re-locate 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.

#### 10. Intended use

- The Hearing Aids are used for hearing compensation of patients with mild to moderate air conduction hearing loss.

#### 11. Contraindication

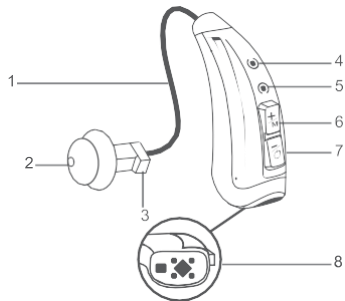
- The device is unsuitable and should not be used in the following situations:
  - (1) Patients with chronic suppurative otitis media, congenital ear atresia to banned use.
  - (2) This hearing aids only be used for compensating the patients with hearing impairment, do not have hearing therapeutic value.

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## GET TO KNOW YOUR DEVICE

### Hearing aids



1.Ear Tube

2.Eartip

3.Speaker unit

4.Microphone 1

5.Microphone 2

6.Increase volume / Program switch

7.Decrease volume / Power On / Off

8.Charging contacts

## 1. 【HOW TO APPLY EARTIPS IT IS】

Please follow the following steps to apply eartips. The eartips may remain in the ear canal with incorrect replacement while taking the hearing aids off the ear, which will cause hearing damage.

Step 1:

Choose a suitable size of eartips.



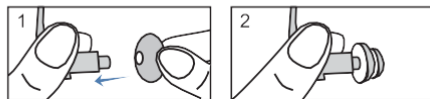
Step 2:

Push the eartips rim membrane outward.



Step 3:

Hold on to the end of the ear tube and push firmly to ensure that the eartip is fastened securely.

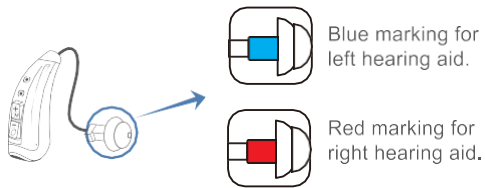


Notes:

After the eartip is installed, pull the eartip gently to see if it is firmly installed and ensure the eartip does not fall off easily.

## 2. 【LEFT & RIGHT HEARING AID MARKINGS】

There is a red or blue marking on the ear tube, which helps to distinguish between left and right hearing aid.

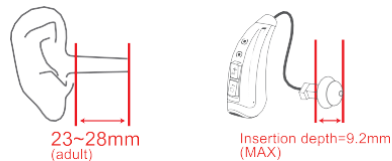


## 3. 【INSTRUCTION FOR INSERTION DEPTH】

For adults, the average length of the ear canal has been estimated to be 23-28 mm and the maximum insertion size of the hearing aid is 9.2mm.

So the distance from the eartip to the tympanic membrane after wearing the hearing aid is at least 13.8mm, which is greater than the lower limit of 10mm specified by OTC.

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



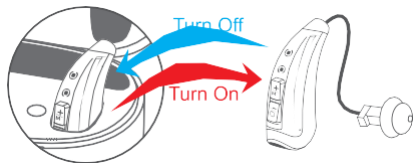
#### 4. 【TURN ON/OFF】

- There are two ways to turn on/off the hearing aids


##### 4.1

Turn on: When you remove the hearing aids from the charging case, they will turn on automatically. You will hear prompt tone according to the hearing program(refer to "PROGRAMS SWITCHING").


Turn off: When you place the hearing aids back into the charging case, they will turn off automatically and start charging.



##### 4.2 Turn ON:

Turn on your hearing aids by pressing the  button for about three (3) seconds. You will hear notification sound "POWER ON".

##### Turn OFF:

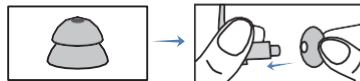
Turn off your hearing aids by pressing the  button for about three (3) seconds. You will hear notification sound "POWER OFF".

#### 5. 【WEAR/REMOVE HEARING AIDS】

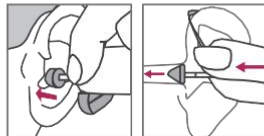
##### 5.1 Wearing hearing aids

- Keep the hearing aids off before wearing or removing.

Step 1: Choose a suitable size of eartips and mount it in your hearing aids.



Step 2: Push the eartip into the ear canal until you feel snug.



Step 3: Gently put the hearing aids over your ear until it rests securely behind your ear.



## 5.2 Removing hearing aids

Step 1: Turn off the hearing aids

Step 2: Using your thumb and index finger, gently pull the eartips from the ear canal.

Step 3: Take the hearing aids away from your ear.

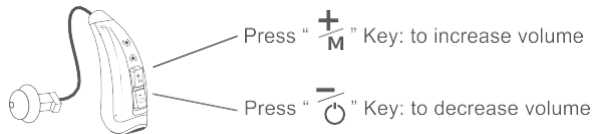


Notes:

- Hearing aids will whistle when inserted incorrectly. Reinserting them into your ear canal correctly .
- If whistling remains after reinsertion, replace the eartips with another size and try it again.
- If the hearing aids doesn't work properly, please check the "TROUBLESHOOTING GUIDE". If none of the solutions works, contact our service team.

## 6. 【VOLUME CONTROL】

- The hearing aids have eleven(11) volume levels.
- You could increase the volume level by pressing the button  $\frac{+}{M}$  once. The hearing aids will give out the prompt tone "Beep".
- You could decrease the volume level by pressing the button  $\frac{-}{\text{power}}$  once. The hearing aids will give out the prompt tone "Beep".
- The hearing aids will give out the prompt tone "Beep-Beep-Beep" at maximum or minimum volume.
- Low battery warning: You will hear the prompt tone when the remaining battery capacity is almost used out.



## 7. 【BLUETOOTH】

Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc.

### 7.1 Bluetooth connection

- Be sure Bluetooth is available on your phone.

Step 1: Turn on your hearing aids before connecting Bluetooth.

Step 2: Check the Bluetooth setting on your phone to "Pair New Device".

Step 3: Select device name "OTC Clarity Units" to pair(connect) the Bluetooth of your phone.

Connection status	Prompt tone
Connect successfully	Connected
Disconnected	Disconnect

- Accept any prompts given by your phone regarding the Bluetooth connection.

Notes:


Once the first pairing is done, the hearing aids will reconnect to your phone automatically as long as Bluetooth of your phone is available.


Attention:

Do not use the Bluetooth function of your hearing aids for any medical purposes.


### 7.1 Bluetooth connection


#### 1. Listening to music

- You could increase the music volume by short pressing button  once.

- You could decrease the music volume by short pressing button  once.


#### 2. Phone calls

- Answer the incoming call by short pressing button  once.

- Reject the incoming phone call by long pressing the button  for about 1.5 seconds.

- Hang up the phone call by long pressing the button  for about 1.5 seconds.

## 8. 【PROGRAMS SWITCHING】

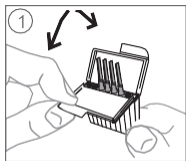
- There are four(4) preset programs in the hearing aids.
- You could switch the hearing programs by pressing the button  for about three(3) seconds.
- Different programs have different beeps as below.

Hearing program		Prompt tone
1	Normal	Beep
2	Restaurant	Beep Beep
3	Outdoor	Beep Beep Beep
4	Music	Beep Beep Beep Beep

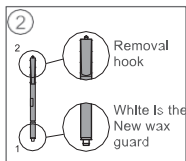
The hearing aids are designed with the memory function: The last setting can be remembered when the hearing aids turned off.

### 9. 【HOW TO CHANGE THE WAX GUARD】

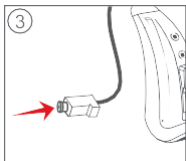
- Wax guard helps to protect the hearing aids from earwax.
- Wax guard is a disposable good that should be thrown away after used.
- The manufacturer do NOT supply additional wax guards with your hearing aids. If you need it, please buy it from your healthcare professional or somewhere else.
- Please follow the following steps to change the wax guard.



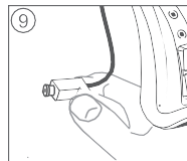
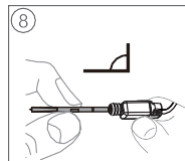
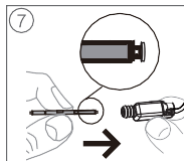
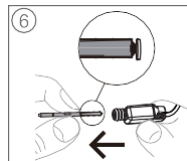
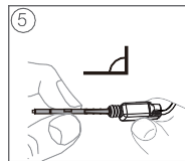
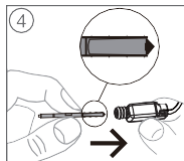
Open the wax guard case as illustrated



Take out the earwax baffle



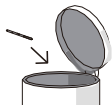
Hearing aid wax guard position



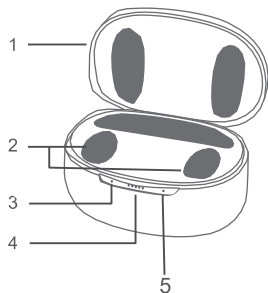
Insert the removal hook into the used wax guard. Keep the holder at a right angle. Pull the used wax guard straight out.

Insert the new wax guard into the opening of the sound outlet and press it gently and pull the holder straight out

- Throw away the used wax guard.
- If the wax guard can not be locked on the hearing aids, please replace the new wax guard.



## 10. 【CHARGING】



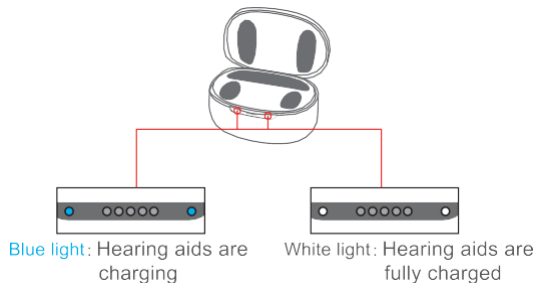
1. Upper Cover
2. Charging slot of the hearing aids
3. Left-side hearing aid charging indicator
4. Charging case charging indicator
5. Right-side hearing aid charging indicator

### 10.1 Charging the hearing aids

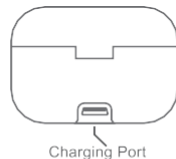
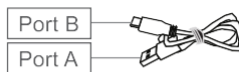
Step 1: Place your hearing aids back into the correct slot of the charging case.

Step 2: The hearing aids will start charging automatically.

- Blue indicator light indicates that the hearing aids are charging.
- White indicator light indicates that the hearing aids are fully charged.



### 10.2 Charging the charging case

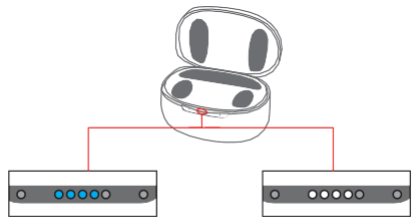


Step 1: Connect the B port of the USB cable to the charging port of the charging case.

Step 2: Connect the A port of the USB cable to the power supply.

- Blue light indicator that the charging case is charging.
- White light indicates that the charging case is fully charged.

- **Blue light** indicates that the charging case is charging.
- **White light** indicates that the charging case is fully charged.

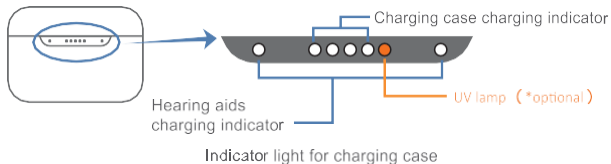


**Blue light:** Charging case is charging

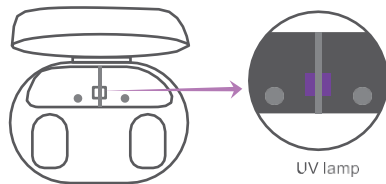
**White light:** Charging case is fully charged

### 10.3 The UV lamp sterilization function(\*optional)

- The UV lamp has the sterilization function and can sterilize bacteria such as Escherichia coli, Staphylococcus aureus, Staphylococcus albus and the like.



- The sterilization function of UV lamp will be activated for about ten(10) minutes when the hearing aids start charging



**⚠ Safety tips:** During the use of the UV lamp, please do NOT irradiate the human body to avoid accidental injury.

\*The data are derived from the measured value of the product at the laboratory, not guaranteed values.

- The charging case will charge the hearing aids whatever the upper cover is open or closed. The charging process will stop automatically when the case and hearing aids are fully charged.
- Check the "TROUBLESHOOTING GUIDE" when failure occurs to your devices.

## 10.4 OTC Clarity APP

Step 1: Tap to start “App Store” or “Google Play Store” on a compatible Apple or Android device.

Step 2: Search “OTC Clarity”.

Step 3: Tap “GET” to download the “OTC Clarity” APP. Follow the system prompts to finish the installation.

Step 4: Tap to start the “OTC Clarity” APP.

Step 5: Follow the novice guide to finish the setup.

Step 6: Start to personalize and fine-tune your hearing aid.



Further instruction is available on OTC Clarity APP (“More”—“Help”).

\*Requirement for running the app: iOS 14 or later; Android 5.0 or later.

\*Android™, Google Play and the Google Play logo are trademarks of Google LLC.

Apple, the Apple logo, iPhone, iPad and iPod touch are trademarks of Apple Inc.

App Store is a service mark of Apple Inc.

IOS is a trademark of Cisco.

## 11. 【HOW TO CARE FOR YOUR DEVICES】

Please follow the advice below for the best user experience and to prolong the life of your devices.

- Do not drop your hearing aids or knock them against hard surfaces.
- Do not use sharp tools to dislodge ear wax. Sticking household items into your devices can seriously damage them.
- Keep your devices away from high-temperature and/or high-humidity atmosphere.
- Do not swim, shower or sauna while wearing the hearing aids.
- Do not attempt to dry the hearing aids or charging case in an oven, microwave or other heating equipment. This will cause them to melt and may cause burns to your skin.
- Always remove your hearing aids when using hair care products. The hearing aids can become clogged and cease to function properly.
- Store your devices in a clean and dry location
- Do not use the electronic dryer to store the rechargeable hearing aids.
- Inspect the hearing aids, eartips, and charging case regularly. Remove earwax and debris from your devices by using enclosed cleaning tools.
- Clean the charging contacts of the rechargeable hearing aids with cleaning cloth regularly to ensure the normal charging.
- Eartips should be replaced every 3-6 months or when they become stiff, brittle, or discolored.

## 12. 【TROUBLESHOOTING GUIDE】

### 12.1 Troubleshooting

#### 12.1.1 Hearing aids fault self-checking table

Issue	Possible Causes	Potential solution
Feedback or “whistling”	Are the hearing aids worn correctly in your ears?	Wear the hearing aids in your ears.
	Is the volume very loud?	Reduce the volume.
	Are the eartips broken or clogged?	Replace the eartips
	Are you holding an object close to the hearing aids?	Move your hand away to create more space between the hearing aids and the objects.
	Is your ear full of wax?	Visit your physician.

Issue	Possible Causes	Potential solution
No sound	Pressing time is too short to turn on hearing aids.	Turn on your hearing aids in the right way.
	Remaining battery capacity is used out.	Charge the hearing aids.
	Microphone is clogged.	Clean debris or earwax from microphone.
Voice is weak or fuzzy	Low battery	Charge the hearing aids.
	Volume is too low.	Increase the volume level.
	Microphone is clogged.	Clean debris or earwax from microphone.
Scan or search the Bluetooth of hearing aids unsuccessfully	Misrecognize the Bluetooth broadcast name.	Bluetooth broadcast name: OTC Clarity Units
	Bluetooth function of your mobile device is OFF.	Turn on the Bluetooth function of your mobile device.

Issue	Possible Causes	Potential solution
Scan or search the Bluetooth of hearing aids unsuccessfully	Hearing aids is occupied by other mobile device.	Disconnect from other mobile device and try to connect again.
Can not operate and adjust your hearing aids via APP after connecting to your mobile device successfully	Hearing aids are not connected to the APP	Connect your hearing aids to the APP
Music or phone function is not working after connecting successfully	Hearing aids do not get the permission of your mobile device about media or phone.	Set permission to your hearing aids
	Do-not-disturb mode of your mobile device is ON.	Turn off the Do-not disturb mode of your mobile device.

### 12.1.2 Charging case fault self-checking table

Issue	Possible Causes	Potential solution
Indicator light of charging case is not light up or flashing.	Adapter is not powered	Power the adapter or replug to the power supply.
	Charging case is connect to the USB cable incorrectly.	Check and connect charging case to USB cable correctly.
Charging case can not charge the hearing aids.	Hearing aids are not inserted into the correct slot of charging case.	Insert hearing aids into the correct slot of charging case to charge.
	Charging contacts are dirty	Clean the charging contacts of hearing aids and charging case.

## 12.2 Technical specifications

Test Standard: ANSI 3.22-2014

Test Equipment: FONIX 8000

Test Coupler: HA-1

The standard test ambient conditions shall be:

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

Relative humidity: 0% to 80%

Atmospheric pressure:  $760(+37.5, -150)\text{mm of Hg}$  or  $101.3(+5, -20)\text{kPa}$

1). OTC Hearing aids technical specifications	
Test Item	Program 4
Max. Output(OSPL90)	114dB
Average saturation out put (HFA-OSPL90)	111dB
The total harmonic distortion value(THD)	2%
The full-on gain value (HFA FOG@50)	40dB
Equivalent input noise level(EIN)	29dB
Frequency response bandwidth (Not narrower than)	200~6250Hz

2). Battery life	
Test Items	Value
Battery life of hearing aids	22h
Operation environment	Temperature: $-10\text{ C} \sim 40^{\circ} \text{C}$ , Relative humidity: 30%-75%RH, Atmospheric pressure range: 86~106kPa
Storage & transportation environment	Temperature: $-10\text{ C} \sim +55\text{ C}$ , Relative humidity 10%-90%, Atmospheric pressure range: 70-106kPa

\*The actual battery life depends on battery quality, use pattern, active feature set, hearing loss and sound environment.

\*The data are derived from the measured value of the product at the laboratory, not guaranteed values.

## 12.3 ACCESSORIES LIST

Hearing Aids: 2

Eartips: 10

Cleaning Tool: 1

Manual: 1

USB Cable: 1

Quick Start Guide: 1

## 12.4 Regulatory and legal information

This part applies to the product with Bluetooth or APP function. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by manufacturer could void the user's authority to operate this equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not

cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with FCC radiation exposure limits set forth for general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC ID: 2A39M-JH22A61H

Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.

Radio Transceiver Frequency Range: 2.4 to 2.480 GHz

Radio Receiver Bandwidth: 2MHz.

Modulation Type: 1 Mb/s GFSK Peak Effective Isotropic

Radiated Power: 0 dBm.

This equipment has been tested and found to comply with the limits per CISPR 11 class B.

### **Important information regarding Electro Magnetic Compatibility (EMC)**

With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, Medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create

a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

This unit has been thoroughly tested and inspected to assure proper performance and operation! This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the RJADAT-1 unit.

## 1. Guidance and manufacturer's declaration-electromagnetic emission-for all EQUIPMENT and SYSTEMS.

Guidance and manufacturer's declaration-electromagnetic emission

Hearing aids are intended for use in the electromagnetic environment specified below. The customer of the user of hearing aids should assure that it is used in such an environment.

Emission test	Classified / Test Level	Compliance	Electromagnetic environment – guidance
Power line conducted emission test	CISPR 11, Class B, Group 1	N/A	Hearing aids use RF energy only for its internal - function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Radiated emission test	CISPR 11, Class B , Group 1	Pass	The hearing-aids are suitable for use in all establishments, other domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emission test	IEC 61000-3-2, Class A	N/A	
Voltage fluctuations & flicker emissions	IEC 61000-3-3	N/A	

## 2. Guidance and manufacturer's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity for all equipment and systems.		
Hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of hearing aids should assure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ± 8 kV  Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ± 8 kV  Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV

Radiated RF electromagnetic fields immunity test	10V/m,80MHz -2.7GHz 80% AM at 1KHz RF Band(IEC 60601-1-2:2014+A1:2020 section 8.10 table 9)	10V/m,80MHz -2.7GHz 80% AM at 1KHz RF Band(IEC 60601-1-2:2014+A1:2020 section 8.10 table 9)
Electrical fast transient and burst test IEC 61000-4-4	AC port:±2 kV Patient coupling port: ±1 kV 100kHz repetition frequency	N/A
Surge test IEC 61000-4-5	Line to line: ±500V, ±1kV Line to ground: ±500V,±1kV,±2 kV	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m, 50Hz and 60Hz	30 A/m, 50Hz and 60Hz

Voltage dips, and interruption IEC 61000-4-11	0% UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	N/A
	0% UT; 1cycle and 70% UT; 25 cycles Single phase: at 0°	
	0% UT; 250 cycles	
Proximity magnetic fields immunity test	IEC 60601-1-2: 2014+A1:2020 section 8.11 table 11	IEC 60601-1-2: 2014+A1:2020 section 8.11 table 11
NOTE UT is the a.c. mains voltage prior to application of the test level.		

### 3. Guidance and manufacturer's declaration–electromagnetic immunity-for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration-electromagnetic immunity for equipment and system that are not life-supporting

The hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of hearing aids should assure that it is used in such an environment.

Immunity test	Conducted RF IEC 61000-4-6	Radiated RF IEC 61000-4-3
IEC 60601 test level	10 Vrms 150 kHz to 80 MHz	10V/m 80 MHz to 2.5 GHz
Compliance level	10 Vrms	10V/m 80 MHz to 2.5 GHz

Electromagnetic environment –guidance

Portable and mobile RF communications equipment should be used no closer to any part of hearing aid treatment device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

#### Recommended separation distance


$$d=1.2\sqrt{P}$$

$$d=1.2\sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$$

$$d=2.3\sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$$

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup>

Interference may occur in the vicinity of equipment marked with the following symbol: 

**NOTE1:**

At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE2:**

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which hearing aids are used exceeds the applicable RF compliance level above, hearing aids should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating hearing aids.

b. Over the frequency range 150kHz to 80MHz, fields strengths should be less than 3V/m.

#### 4. Recommended separation distances between portable and mobile RF communications equipment and hearing aid

Hearing aids are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of hearing aids can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and hearing aids as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.















**NOTE 1:**

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE2:**

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 12.5 Normalized symbols

	Follow operating instructions		
	B type applied part		
	Disposal in accordance with Directive 2012/19/EU (WEEE)		
	Date of manufacture		Manufacturer information
	Serial number		USE BY
	Warning/ Danger: Improper use might cause serious injuries.		
	Medical Device		
	Permissible storage and transport temperature and humidity		
	Permissible operating temperature and humidity		
	Keep Dry		Comply with Directive 2011/65/EU
	Paper Packaging Recycling		

Notes: This hearing aid is produced for Oxiline LLC under the strict quality control of Jinghao Medical Technology Co., Ltd.

- The device fulfills the provisions of the Harmonize Standard as IEC 60601-1, IEC60601-2-66, IEC60118-7, IEC 60118-13, ISO 10993-1/-5/-10 ISO 14971.

## 12.6 Maintenance, cleaning, 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.

### ● Cleaning

- 1) Cleaning the ear tips

Remove any earwax buildup using the clean stick.

Wipe clean with a tissue or soft cloth.

- 2) Cleaning hearing aids

Use a soft cloth or tissue to wipe any moisture, perspiration, or debris from the surface of the hearing aids.

Note: Do not use alcohol or other cleaning solvents to clean the hearing aids as this could damage the protective covering.

### ● 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) The hearing aids should be fully charged before using for the first time. Do not store the hearing aids for extended periods of time without recharging them (max. six months).

### ● Disposal




Please dispose of the device in accordance with the directive 2012/19/EU - WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please refer to your local authority responsible for waste disposal.


## 12.7 Product Lifetime Warranty

Oxiline sells its products with the intent that they are free of defects in manufacture and workmanship for life, except as noted below. Oxiline warrants that its products will be free of defects in material and workmanship under normal use and service. This warranty extends only to consumers and does not extend to retailers.

To obtain warranty service on your Oxiline product, contact a Consumer Relations representative for assistance. Please make sure to have the model number of the product available.

This warranty does not extend to the purchase of opened, used, repaired, repackaged, and/or resealed products, including but not limited to sale of such products on internet auction sites and/or sales of such products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate as to any products or parts thereof that are repaired, replaced, altered, or modified, without the prior express and written consent of Oxiline.

 Manufactured for Oxiline LLC  
140 NW 37th St. 33127 Miami, FL  
Email: support@oxiline.shop  
Call: +1 (833) 694-5463  
Hours: Mon-Fri 9:00 AM - 5:00 PM Eastern Time

CERTIFICATE	
Product Name	Hearing Aid
Product Life	5 years
Model	JH-DW3F
Lot No.	Outside packaging
Inspector	
The product conforms to the national and industrial standards and has passed inspection.	

