

## **Compatible Devices**

The Otofonix app is available for iPads and iPhones with iOS version 9 and higher or for Android devices running version 6 or higher. Bluetooth, The Bluetooth® word mark, and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Otofonix is under license. Other trademarks and trade names are those of their respective owners.

## **Warnings**

Notifications of app updates should not be disabled, and it is recommended that the user installs all updates to ensure that the app will function correctly and will be kept up to date. The app must only be used with the Otofonix device for which it is intended, and Otofonix

01

warning signals, e.g. in traffic.

## **X-ray, MRT, CT, PET Scanning,**

### **Electro-therapy**

- Hearing devices must not be exposed to strong electrical fields that may be generated during X-rays, CT scans, PET scans or MRTs, during electrotherapy or during surgeries. Please remove your hearing devices in these types of situations to prevent any damage to them.

Explosion Hazard

- Under normal conditions, hearing device batteries do not cause any fires. Hearing devices were not tested for compliance with international standards in explosion-conductive atmospheres.

06

takes no responsibility if the app is used with other devices. If using the Otofonix app with the hearing device, please make sure to read the hearing device user guide. The hearing device user guide was included in the hearing device package. If you need a new copy, please contact Otofonix customer support. Mobile device apps are intended to be used with wireless hearing devices. Mobile device apps send and receive signals from the wireless hearing devices via mobile devices for which the apps have been developed.

## **Hazard Warnings**

- Prevent other people from using your hearing devices as these were individually adjusted to your hearing and may result in permanent

02

- Do not use your hearing devices in explosion hazard areas.

## **Batteries**

- Ensure proper and careful disposal of batteries. Dispose of used batteries as you would other electronic waste that potentially contains rare earth metals.

- Never leave hearing devices or batteries where small children and pets can

reach them. If batteries are swallowed, consult your physician or local poison control center immediately.

- Do not recharge batteries that are not intended for recharging.

07

hearing damage in the event of misuse by another person.

- Hearing devices will not restore normal hearing and will not prevent or improve a hearing impairment resulting from

organic conditions.

- In most cases, infrequent use of a hearing device does not provide full benefit. Once you have become used to wearing your hearing devices, wearyour hearing devices all day every day.

- The use of hearing devices is only part of hearing rehabilitation; auditory training, lip reading instruction, and learning to interpret gesture cues may be required.

- Allergic reactions to hearing devices are unlikely. If you experience itching, redness,

03

Leaking batteries result in the creation of harmful substances. Please be very careful and avoid skin contact with these substances. If there is leakage on skin or in ear, seek medical assistance immediately. If there is leakage on the hearing device, return it to manufacturer for evaluation.

## **Microphone Mode**

- Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e.g. cars, are partially or entirely suppressed.

08

soreness, inflammation, or a burning sensation in or around your ears, inform your hearing healthcare professional and contact your physician.

- In the unlikely case that any parts remain in the ear canal after the

removal of the hearing device, contact a physician immediately. Not doing so

could lead to infection.

Your hearing devices use the most modern components to provide the best possible sound quality in every listening situation. However, communication devices such as digital cell phones can create interference (a

buzzing sound) in hearing devices. If you experience interference from a cell phone being

04

## **Bluetooth Use/Airplane Mode**

- Your hearing devices use Bluetooth.

Airplane mode must be activated when you are in an area where Bluetooth use is not permitted.

- Airplane mode is enabled by closing the battery door whilst holding the push-button in the down position.

## **Warning to Hearing Device Dispensers**

A hearing device dispenser should advise a prospective hearing device user to consult

09

used close by, you can minimize this interference in a number of ways. Switch your hearing devices to another program, turn your head in a different direction, or locate the cell phone and move away from it.

- Do not modify this equipment without authorization of the manufacturer.

- Never use your hearing devices when engaging in contact sports. The risk of injury is very high in the event of a knock on an ear with a hearing device.

- Hearing devices should only be used as directed by your physician or hearing health-care professional.

- Hearing devices may fail suddenly and without prior warning (e.g. in case of a defect or an empty battery), particularly in situations where you are required to hear acoustic

05

promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing device if the hearing device dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible congenital or traumatic deformity of the ear.

- History of active drainage from the ear within the previous 90 days.

- History of sudden or rapidly progressive hearing loss within the previous 90 days.

- Acute or chronic dizziness.

- Pain or discomfort in the ear.

- Unilateral hearing loss of sudden or recent

10

onset within the previous 90 days.

- Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1000 Hz, and 2000 Hz.

- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

Stop using the Otofonix Sona and consult a physician if:

- Hearing in one or both ears worsens.
- Hearing does not improve.
- Skin irritation develops in or around your ear canal.
- Your ear becomes occluded with excessive ear wax.

child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

**FCC Regulations**

Per FCC 15.19(a)(3) and (a)(4), this device complies with part 15 of the

FCC Rules. Operation is subject to the following 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.

Note: The manufacturer is not responsible for

- You develop an infection of your ear or ear canal.

Special care should be exercised in selecting and fitting a hearing device whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing device user.

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit from it. The use of hearing devices is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lip reading.

any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

Radio Equipment Directive

Information:

The equipment operates in the ISM GHz band (X.XX – X.XXXX GHz), using the Bluetooth™ SMART protocol, and the maximum RF Power transmitted in that band is XX.X dBm EIRP.

Manufactured for Otofonix by

XXXXXX

FCC ID: XXXXXXXXXX

**Important Notice For Users**

Good health practice requires that a person with hearing loss has a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing device. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of a medical evaluation is to assure that all medically treatable conditions that

may affect hearing are identified and treated before the hearing device is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing device. The physician

**Transport and Storage Conditions**

During transport or storage for a long period of time, the temperature should not exceed the limit values of 14° to 158° Fahrenheit (-10° to 70° Celsius).

During transport or storage for a long period of time, the relative humidity

should not exceed the limit values of 10% to 60%.

The air pressure range between 500 and 1100 hPa is appropriate or the

hearing device performance could be affected.

will refer you to an audiologist or a hearing device dispenser, as appropriate, for a hearing device evaluation.

The audiologist or hearing device dispenser will conduct a hearing device evaluation to assess your ability to hear with and without a hearing device. The hearing device evaluation will enable the audiologist or dispenser to select and fit a hearing device to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial or purchase program. Many hearing device dispensers now offer programs that permit you to wear a hearing device for a period of time for a fee after which you may decide if you want to purchase the hearing device. Federal law restricts the sale of hearing devices to those individuals who have obtained a medical evaluation from a licensed

**Compliance Information**

 The symbol with the crossed-out garbage bin is to make you aware that this device may not be thrown away as normal household waste. Please dispose of old or unused devices at waste disposal sites intended for electronic waste, or give your device to your hearing healthcare professional for disposal. Proper disposal protects the environment and health.

 Symbol for caution. This is a safety symbol used to highlight that there are specific warnings or precautions associated with the devices that are not otherwise found on the label.

 Symbol for keep dry.

 Symbol for fragile, handle with care.

physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician.

The exercise of such a waiver (without prior consultation by an ear specialist) is not in your best health interest and its use is strongly discouraged.

**Children with hearing loss**

This product is not for use by anyone under 18 years of age. In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation. Hearing loss may cause problems in language development, educational growth, and social growth of a

 Year of manufacture is the first 2 digits of the serial number (assume 2 digits are preceded by "20"; e.g. "14" = year 2014)

 Serial number is located on part as an 8-digit number. Last 6 digits represent the serial number.