



CONCHA LABS

Concha Sol™ OTC Hearing Aids

Instructions for Use

Document: LBL-001 v 05
February 2024

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

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.

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.

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 the FDA as an adverse event according to the instructions that appear later.

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.

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 constantly need to turn the volume down, you may need to further adjust your device.

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, 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.

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.

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.

Note: Tell the FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to the FDA as soon as possible after the problem. The 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 the FDA.

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1. Intended Use

The Concha Sol OTC self-fitting wireless air conduction hearing aids are intended to amplify sound for individuals with perceived mild to moderate hearing impairment, without the assistance of a hearing care professional or audiogram.

2. Indications For Use

The Concha Sol Hearing Aids are intended to amplify sound for individuals 18 years and older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for use without the assistance of a hearing care professional .



3. Important Safety and Health Information

It is very important to read this user manual and the safety, warnings, and regulatory information thoroughly and completely. Follow safety instructions to avoid damage or injury.



The Concha Sol Hearing Aids are a medical device.



The Concha Sol Hearing Aids may be used multiple times by a single patient.

This product may help you hear better if you strain to follow conversations when others don't, especially in noisy places.

Intended Use Environment

The Concha Sol Hearing Aids are intended to be used for listening to the sounds in a variety of environments (e.g., home, office, transit, social settings, outdoors, etc.). The device should not be used while bathing or swimming (i.e., hearing aids should not be submerged in water).

This product may not be right for you if:

- You feel the hearing aid is not providing enough amplification after fitting the hearing aid multiple times (i.e., creating a Soundscope® profile).
- You consistently experience feedback (squealing / whistling) after fitting the hearing aid multiple times.

A healthcare professional may be able to help you select a different hearing aid solution to meet your needs. You should see a healthcare professional if you:

- Have a visible deformity of the ear.
- Have a current ear infection, a sore in the ear, or a history of active discharge from one or both ears within the past 90 days.
- Have sudden or rapid progression of hearing loss within the past 90 days in one or both ears.
- Have acute or chronic dizziness, poor dexterity, poor vision, or significant dementia.
- Suspect that you have significant earwax accumulation or a foreign object in the ear canal. Symptoms of significant earwax accumulation can include itching in your ear, a feeling of fullness in your ear, and/or reduced hearing.
- Experience pain or discomfort in the ear.
- Have sudden onset or rapid worsening of tinnitus (ringing in the ear) in one or both ears within the past 90 days.

It is good health practice for a person with hearing loss to have a medical evaluation by a licensed physician, preferably a physician who specializes in ear, nose, and throat (ENT). 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 ensure that all medically treatable conditions that may affect hearing are identified and treated.



Warnings, Precautions, and Safety Considerations

For safe and effective operation of the hearing aids, please familiarize yourself with the following information. Please read and keep all safety and use instructions.

NOTE: The hearing aids are designed for personal use.



Warnings

- Over-the-counter hearing aids are only for users who are age 18 or older.
- Concha Sol Hearing Aids are not hearing protection devices.
- Keep the product, components and packaging out of the reach of children, pets, and people with cognitive impairments to prevent accidents such as choking or swallowing.
- Remove the hearing aids from your ears if you encounter overly loud sounds or if they become uncomfortable.




- If you have an active or inactive implant (e.g. defibrillator, pacemaker), follow the implant manufacturer's instructions regarding the use of mobile devices. Hearing aids should be kept at least 6 inches from implantable pacemakers. In the event of malfunctions, stop using your hearing aid and contact your doctor or the implant manufacturer. If you have an active brain implant, ask your doctor or the implant manufacturer for a risk analysis.



- The Concha Sol OTC Hearing Aid is MR Unsafe and could present as a projectile hazard
- Check before using the hearing aids in areas where electronics or wireless devices are restricted. This may cause interference.
- Do NOT resell the hearing aids or share them with others. They are intended for use by a single user.
- Keep the product away from fire and excessive heat (e.g., from storage in direct sunlight, near candles, or in a hot car) to avoid burns or damage to the product.
- Do NOT submerge in water, wear in the shower, or wear while participating in water sports (e.g., swimming, water-skiing, surfing, etc.). Prolonged exposure to water may damage the hearing aids.
- When to see an Ear, Nose, and Throat doctor (ENT)
If you have any of the problems listed below, please see a healthcare professional.
 - 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 within the past 6 months.
 - Your ear feels painful or uncomfortable
 - You have a lot of earwax or you think something could be in your ear
 - You get 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
- 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 at care@conchalabs.com. If your pain or discomfort doesn't go away, contact your healthcare professional.
- Avoid unauthorized modifications to the hearing aids.
- Do not use hearing aids in environments where there is a risk of explosion (e.g. in mines or industrial plants subject to such risk).



Batteries

- Concha Sol Hearing Aids use Zinc Air batteries which are type 312.
 - Batteries in this product are replaceable. Refer to "[Battery Information](#)" for additional information.
 - Hearing aids should not be exposed to temperatures below -4°F (-20°C) or above 140°F (60°C) or when conditions are expected to exceed these temperatures. Using the devices above 140°F could result in overheating, fire, or injury.
 - If abused or misused, the batteries may leak and may cause chemical burns.
 - Do not attempt to recharge your hearing aid batteries.
 - Do not leave batteries in your hearing aid for long periods of time, when not in use. This may cause leakage and erosion.
 - Dispose of batteries in an environmentally friendly way in accordance with Federal and State requirements.
- 
- Keep and store out of reach of children, pets, and people with cognitive impairments. Contains small parts which may be a choking hazard.
 - Ensure that batteries do not come in contact with water.
 - Contents of an opened battery may cause chemical burns to the mouth, esophagus, and gastrointestinal tract. Drink plenty of water.
 - Avoid vomiting and seek immediate medical attention.
 - Keep batteries away from excessive heat such as heaters, fires, and solar radiation as batteries may rupture and release corrosive materials.
 - In the event that a battery ruptures, flush exposed skin with lukewarm water for a minimum of 15 minutes. Obtain immediate medical attention for any exposure to your eyes.
 - Do not touch the contents of a ruptured or dismantled battery
 - Store batteries at room temperature in a dry place.
 - To avoid confusion, do not store batteries with medications that are similar in size and shape.
 - Ensure that loose batteries do not lie around in bulk as this may cause cell shorting and heat build-up.
 - Do not puncture or abuse batteries.
 - Zinc air batteries may release small amounts of zinc oxide to the environment if abused and disposed of improperly.
 - Avoid storing your batteries such that they are in contact with each other. Even with the protective tab attached, contact between batteries can cause them to discharge.
 - Store batteries in a dry, moisture-free environment at room temperature. Do not keep batteries in a refrigerator, in excessively warm areas or in a dehumidifying device. Appropriate battery care reduces the risk of leakage which is harmful to you and your hearing aids, and it saves battery life.
 - Do not cover the battery and/or battery door with any material.
 - Ingestion of a battery can be harmful, never swallow. If ingested seek immediate medical attention or call the NATIONAL BATTERY INGESTION HOTLINE any time on (202) 625-3333.



Precautions

- Hearing aids are designed to be worn with ear tips attached. Do not attempt to insert the hearing aids into your ears without ear tips attached. See section "[Using the Concha Labs Application](#)" for instructions.
- Ear tips are designed to sit comfortably in your ear and should not be forced into your ear at any time. If you experience discomfort or pain, remove from the ear and try an alternative ear tip from the selection provided with the hearing aids. If no suitable ear tip is found after trying all ear tips provided, discontinue use.

- Ear tips are designed to be replaceable. Before fitting the hearing aids to your ears, ensure the ear tips are firmly and securely mounted on the hearing aid. Failure to do so may result in the ear tip becoming lodged in the ear.
- We recommend that only the Concha Labs' ear tips be used with the Concha Sol Hearing Aids as other brands may not fit properly. They also may not mount properly on the hearing aid, which may result in the ear tip separating from the hearing aid and lodging in your ear.
- We recommend that you remove your hearing aids before sleeping. While not harmful, wearing your hearing aids while sleeping can be uncomfortable, disrupt sleep, and drain the batteries. See section [Using the Concha Labs Application](#) for instructions.
- Inspect the ear tips for damage before fitting to the hearing aids and before fitting the hearing aids to the ear. Do not use if the hearing aid or ear tip is damaged. Replacement ear tips can be purchased from Concha Labs.
- Ear wax may build up on the ear tips and hearing aid over time. Regularly inspect the ear tips and hearing aids for ear wax build up. If ear wax is present, follow the instructions in "Care and Maintenance" to remove ear wax. Do not use sharp tools to dislodge ear wax.
- Ear tips need to be replaced approximately every 3-8 weeks. When you notice discoloration, weakening, or small tears, it is time to replace them.
- Ensure ears are clean and dry and free of debris before fitting hearing aids to your ears.
- This is not hearing protection. You should remove the device if you experience overly loud sounds, whether short or long lasting. If you are 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.
- 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. See section "[Using the Concha Labs Application](#)" for instructions.
- Do not stream audio (phone calls, music, podcasts, etc.) using the hearing aids when a high degree of awareness is needed such as when crossing a street, riding a bicycle, or driving.
- 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.

Note: If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a healthcare professional.



Preventing damage and malfunctions to the product

- For safe operation do not submerge the product in liquid. Liquids entering the housing of the product damage the electronics.
- Avoid exposure to extreme temperature (hairdryer, heater, etc).
- Do not store in direct sunlight.
- Avoid exposure to water and salt water.
- Avoid exposure to sand and fine particulates. Inspect product regularly for particulate build up and follow cleaning procedures.
- Only wipe the product with a soft, dry cloth.
- Do not use this product if there are visible sharp edges, cracks, or damage to the housing.
- Keep this product out of windy conditions (e.g., boats, roller coasters, etc.).

Recommended Use and Storage

- The Concha Sol Hearing Aids are wireless Bluetooth® hearing aids intended to be used for wirelessly listening to the world around you.
- Operating conditions: Temperature between 32°F and 104°F (0 °C and 40 °C), humidity between 10% and 90%.
- Recommended storage conditions: Temperature -4°F to 140°F (-20°C to 60°C), humidity between 10% and 60%.

Cybersecurity

Concha Labs has assessed the Concha Sol Hearing Aids from a Cybersecurity perspective, in accordance with FDA guidance. A full risk assessment of the device in regard to cybersecurity revealed no significant vulnerabilities with the product. Based on this assessment, the only action required by the user to ensure the product remains secure is to keep the product updated with the latest product updates from Concha Labs. For information on how to keep your product up to date, please see “Updating the Concha Labs App”. In the unlikely event that your Concha Sol hearing aid has been compromised from a cybersecurity perspective, please reach out to us immediately at care@conchalabs.com for assistance.

Proper operation of the Concha Sol Hearing Aids requires a safe, private, and secure operating environment. To ensure your security, we recommend following best practices for securing your home network and mobile device. For more information, refer to the US Federal Trade Commission’s guidance on online security. Visit: consumer.ftc.gov/topics/online-security

4. What's in the Box

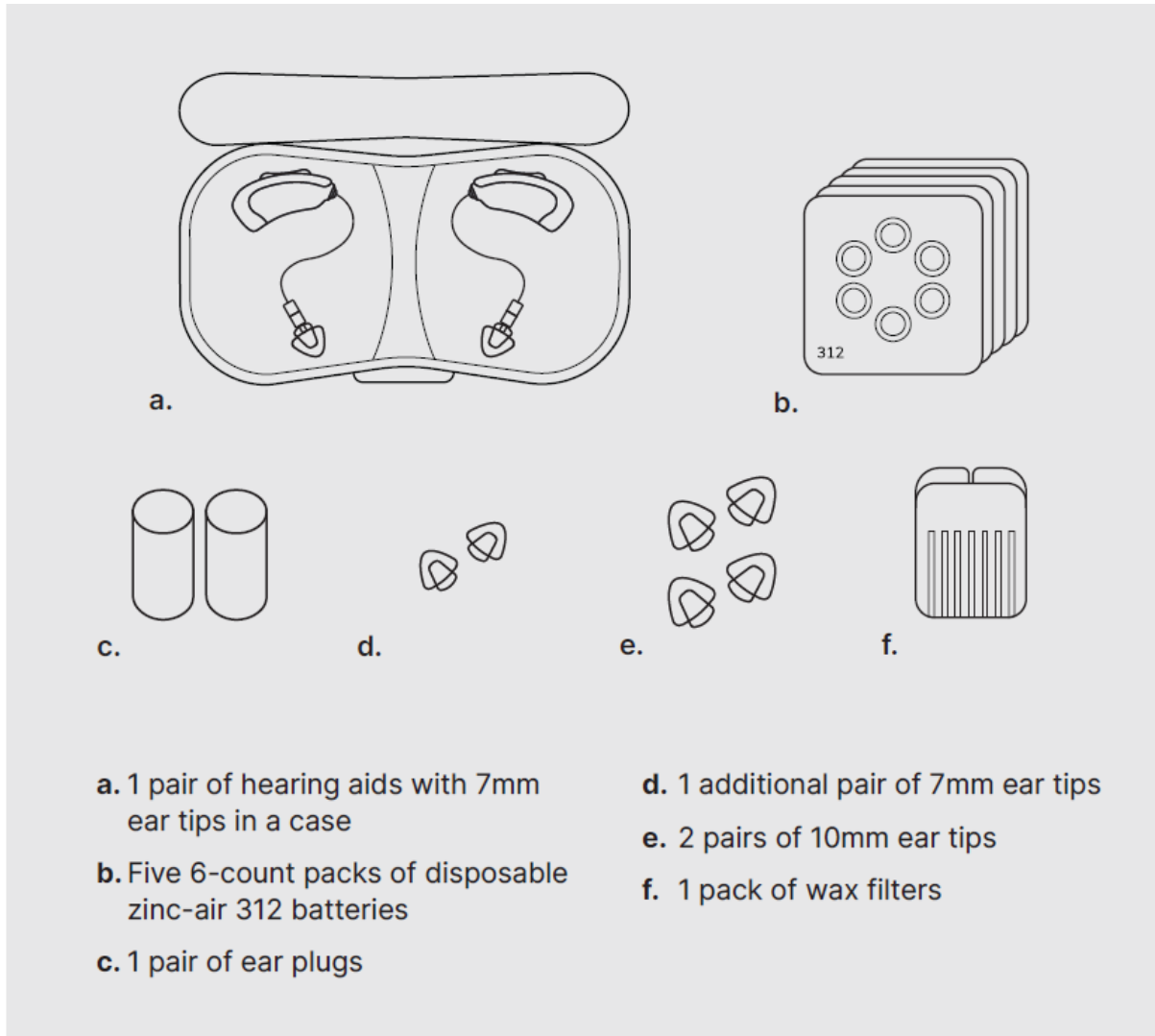


Figure 1: Concha Sol Welcome Box Contents

The Concha Sol Welcome Box also includes:

- Welcome Note, 1 each
- Quick Start Guide, 1 each
- Hearing Aid Case Cover - Download App First Instruction, 1 each

5. Opening the Box

- Remove the tamper evident seal from the package. If a tamper evident seal is not evident, please do not use the product and contact care@conchalabs.com.
- Ensure the components mentioned above are included in the package.
- Extract the Quick Start Guide from the envelope on the inside lid of the box and follow the instructions to download the Concha Labs' mobile application.
- Do not assemble the product until the app has instructed you to do so.

6. The Concha Sol Hearing Aids

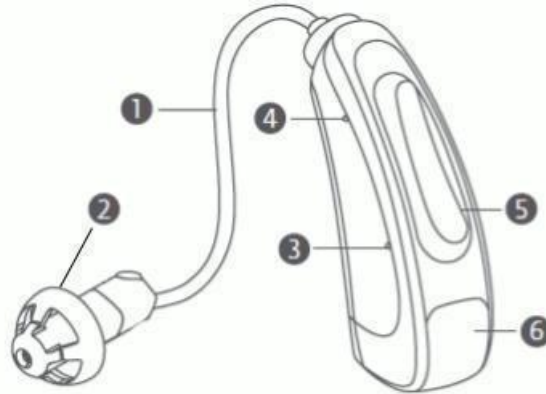


Figure 2: Schematic Diagram of the Concha Sol Hearing Aid: (1) Receiver, (2) Silicon Dome, (3) Rear Microphone Port, (4) Front Microphone Port, (5) Rocker Switch, (6) Battery Compartment

The Concha Sol Hearing Aids incorporates air conduction, and a receiver-in-canal design. The product is also intended to be used in conjunction with a companion app running on a mobile phone (iPhone Model X or later running iOS 15 or later) connected wirelessly to the hearing aids.

7. Concha Labs App Setup and Bluetooth® Pairing

- Download the Concha Labs App by scanning the QR Code located on the Quick Start Guide or by accessing the app via the Apple App Store. Once installed, open the app to begin the setup process.



- All setup instructions will be in the app to guide you. Do not assemble the product until the app has instructed you to do so.
- Proceed with pairing the Concha Sol Hearing Aids and Bluetooth® set up using the Concha Labs App.

7.1. Logging into the Concha Labs App

To use the Concha Labs App you must login. There are two options to login to the mobile application.

- Using an email link: An email will be sent to you. Open it and follow the instructions to automatically be logged in.
- Entering an email and password into the app directly. Your password was created when you purchased and registered the product.
- If you have forgotten your account password, click on the “Forgot Password?” link and follow the instructions in “Changing Your Account Password”.

7.2. Review Required Labelling

The first time you log into the Concha Labs App, the first screen to appear will contain information pertaining to over-the-counter hearing aid controls and associated labelling. You must acknowledge that you have read and understand the information before you will be allowed to proceed.

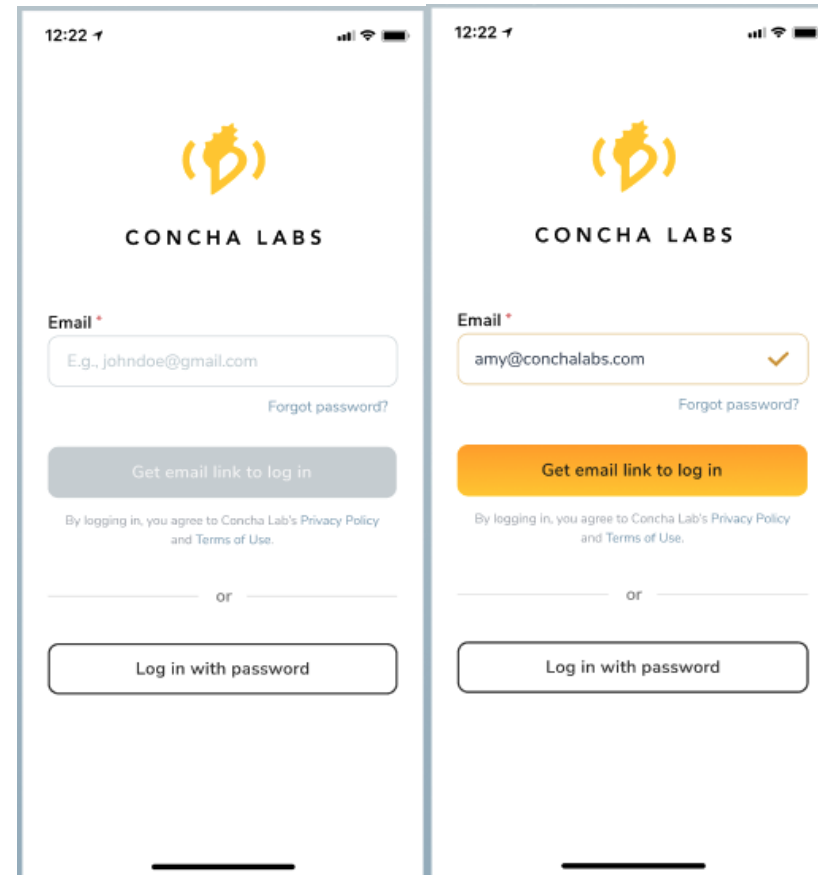


Figure 3: Login Screens

12:22



Concha Sol™ OTC Hearing Aids

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

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 earwax, 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.

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 the FDA as an adverse event according to the instructions that appear later.

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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.

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If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

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.

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to the 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 the FDA.

Technical Specifications

- Maximum Output Limit: 115.2 dB SPL
- Full-On Gain Value: 52.7 dB
- Total Harmonic Distortion: <1%
- Self-Generated Noise Value: 18.7 dB SPL(A)
- Latency Value: 6.7 ms
- Bandwidth: <200 Hz to > 10,000 Hz

I acknowledge that I have read and understand the above information

Continue

Figure 4: Required Labeling Review and Acceptance

7.3. Onboarding the Hearing Aids

Onboarding is performed the first time you access the Concha Labs App. The primary purpose of the onboarding section of the Concha Labs App is to systematically walk you through the setup and configuration of the Concha Sol Hearing Aids including Soundscope, the software that is used for self-fitting of the Concha Sol Hearing Aids and creating a hearing profile. When complete, the Concha Sol Hearing Aids will be ready to be used.

7.3.1. Instructions and Permissions

Follow the on-screen instructions to begin onboarding and grant the app the necessary permissions.

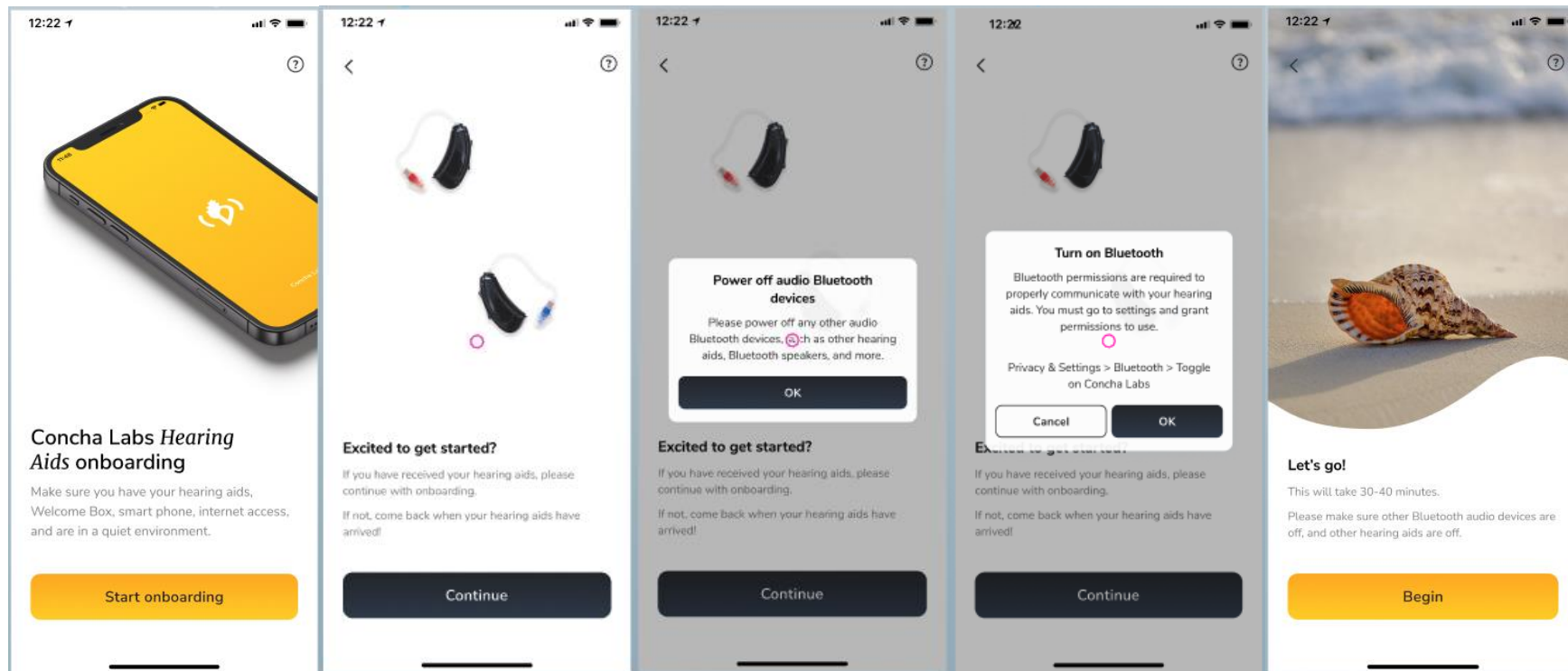


Figure 5: Required Labeling Review and Acceptance

7.3.2. Hearing Aid Tour

After granting the app permissions, a description of the hearing aids and their parts is provided.

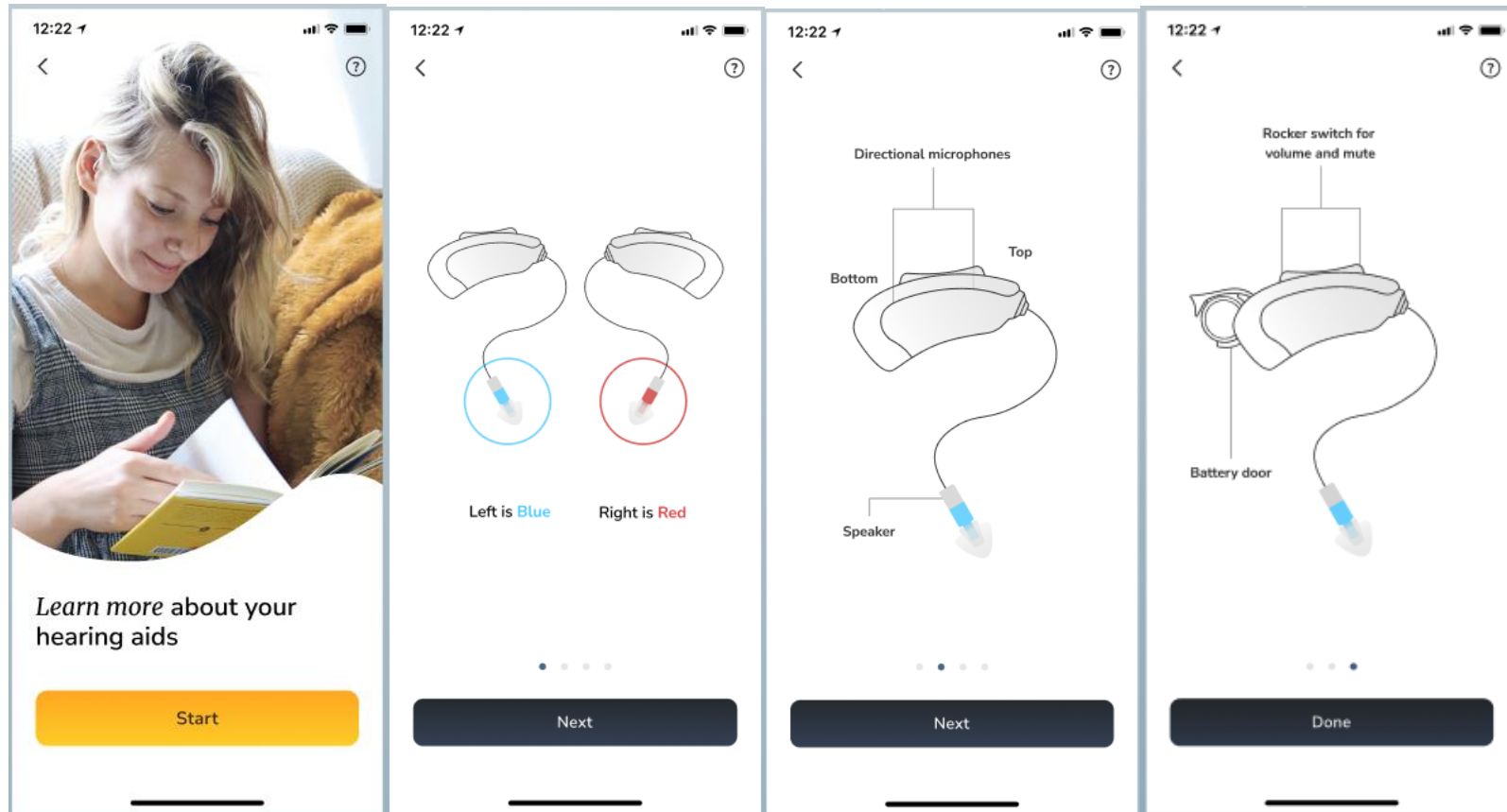


Figure 6: Hearing Aid Tour

7.3.3. Placing the Hearing Aids on Your Ear and Selecting the Correct Ear Tip Size

Ensure that the correct hearing aid is placed in each ear (blue is left and red is right). The hearing aids are inserted into the ear canal in the vertical position with the tip down and then wrapped around the ear towards the back of the head to “lock” them into place and so that the ear tip is positioned properly. The Concha Labs App provides information and a video on how to properly place the hearing aids.

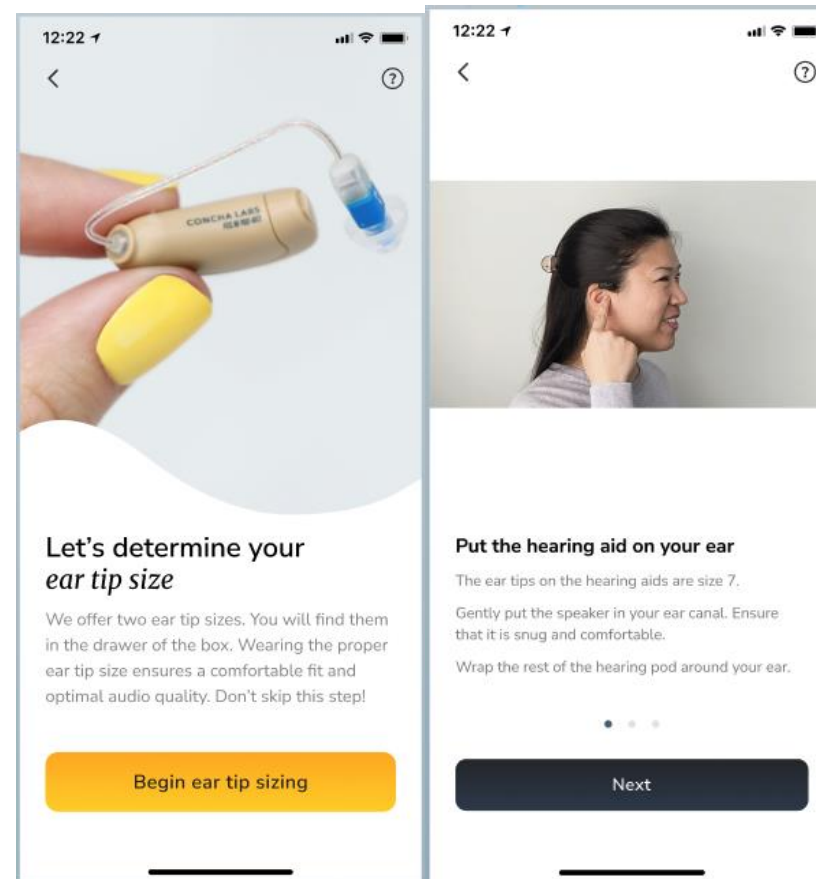


Figure 7: Ear tip and Placement Screens

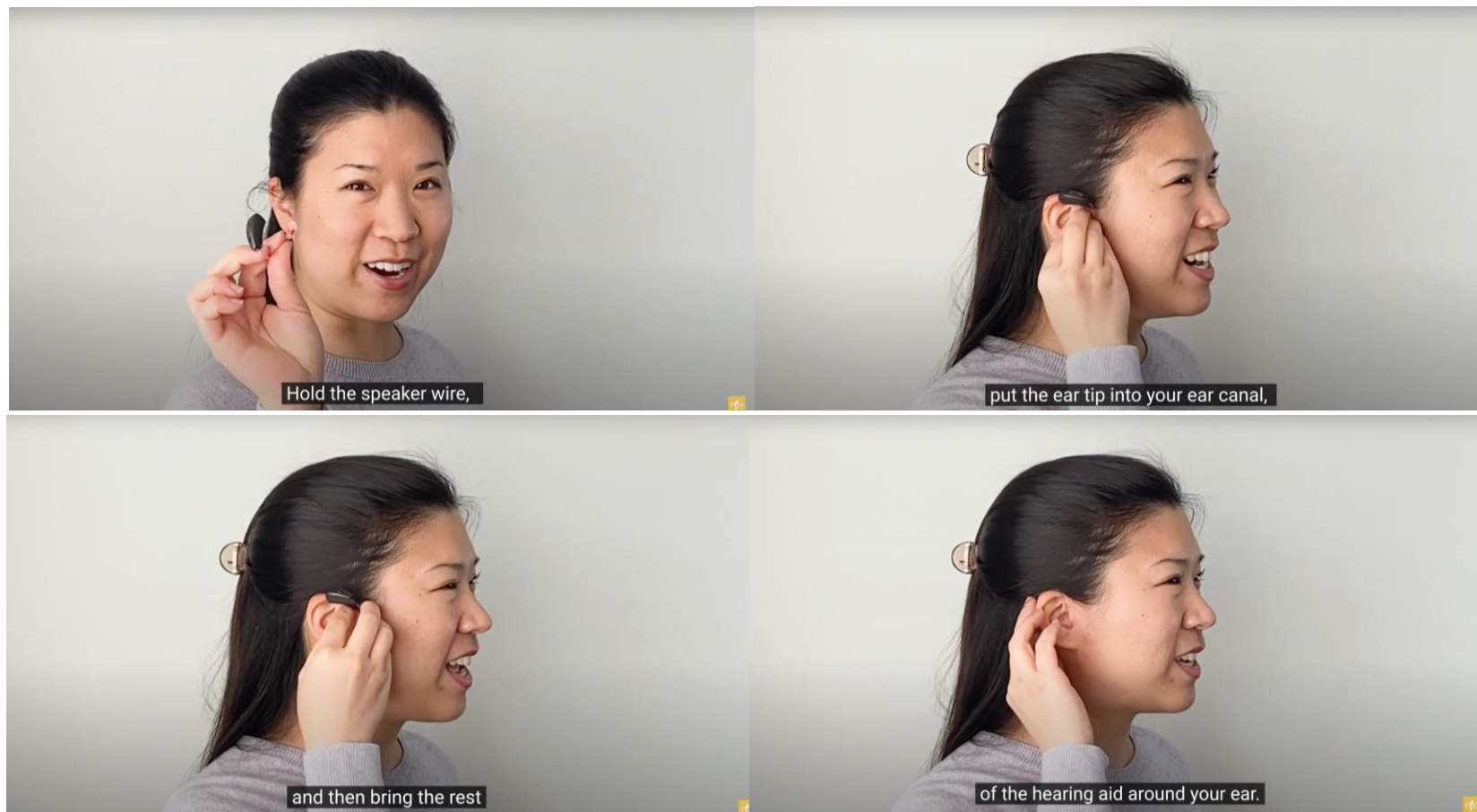


Figure 8: Placing Concha Sol Hearing Aids on Your Ear

It is important to select the ear tip that is the correct size for you. The Concha Sol Hearing Aids come with size 7mm ear tips installed. You should check that you have a good fit as a secure fit is essential for proper operation.

To check the seal, shake your head from side to side and tilt your head to each shoulder. If it feels like the device is falling out of your ear, the ear tip is likely too small for your ear. If it feels like you have to force the device in your ear, the ear tip is likely too large. The Concha Labs App provides information and a video on how to check the fit of an ear tip.

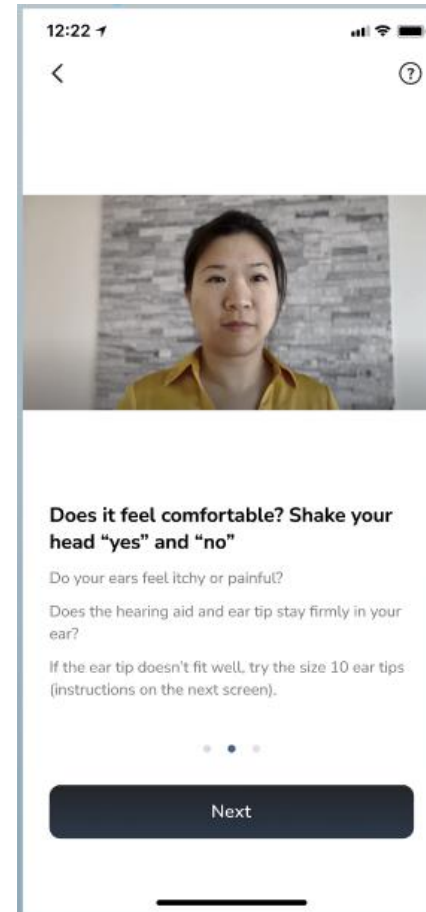


Figure 9: Ear Tip Screen



Figure 10: Checking Ear Tip Fit

The hearing aids come with an additional pair of 7mm ear tips and two pairs of 10mm ear tips. If it feels like the device is falling out of your ear, the ear tip is likely too small for your ear and you should change to the 10mm ear tip. If it feels like you have to force the device in your ear, the ear tip is likely too large. If this happens with the 7mm ear tip, please contact Concha Labs.



Figure 11: Changing Ear Tips Screen

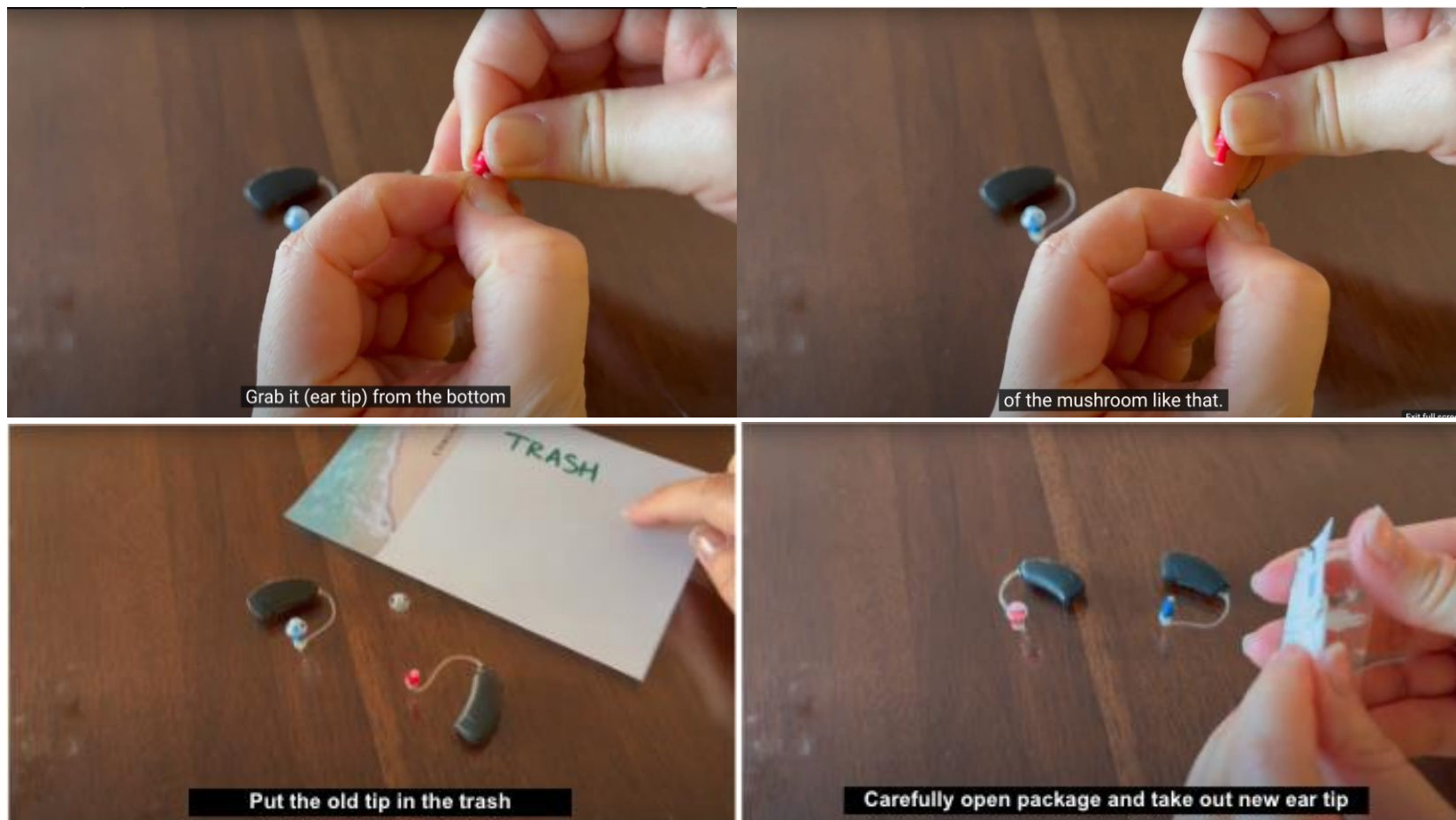


Figure 12: How to change ear tips (if needed) video

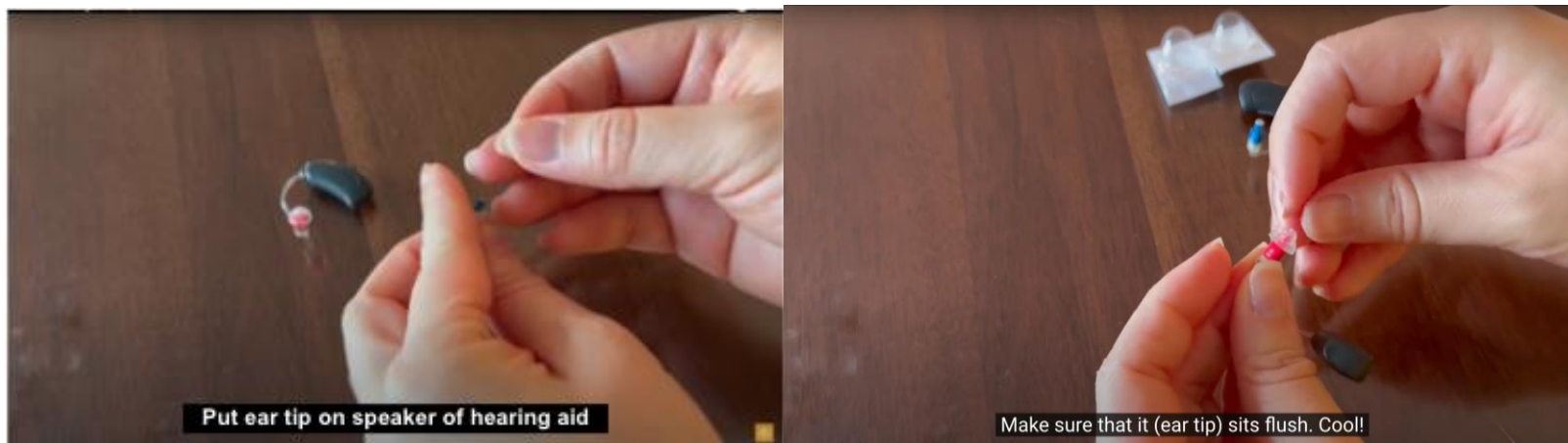


Figure 13: How to change ear tips (if needed) video (continued)

The app will ask you to select which ear tip size you prefer and record your answer in your account so that you can order the correct size when replacements are needed.

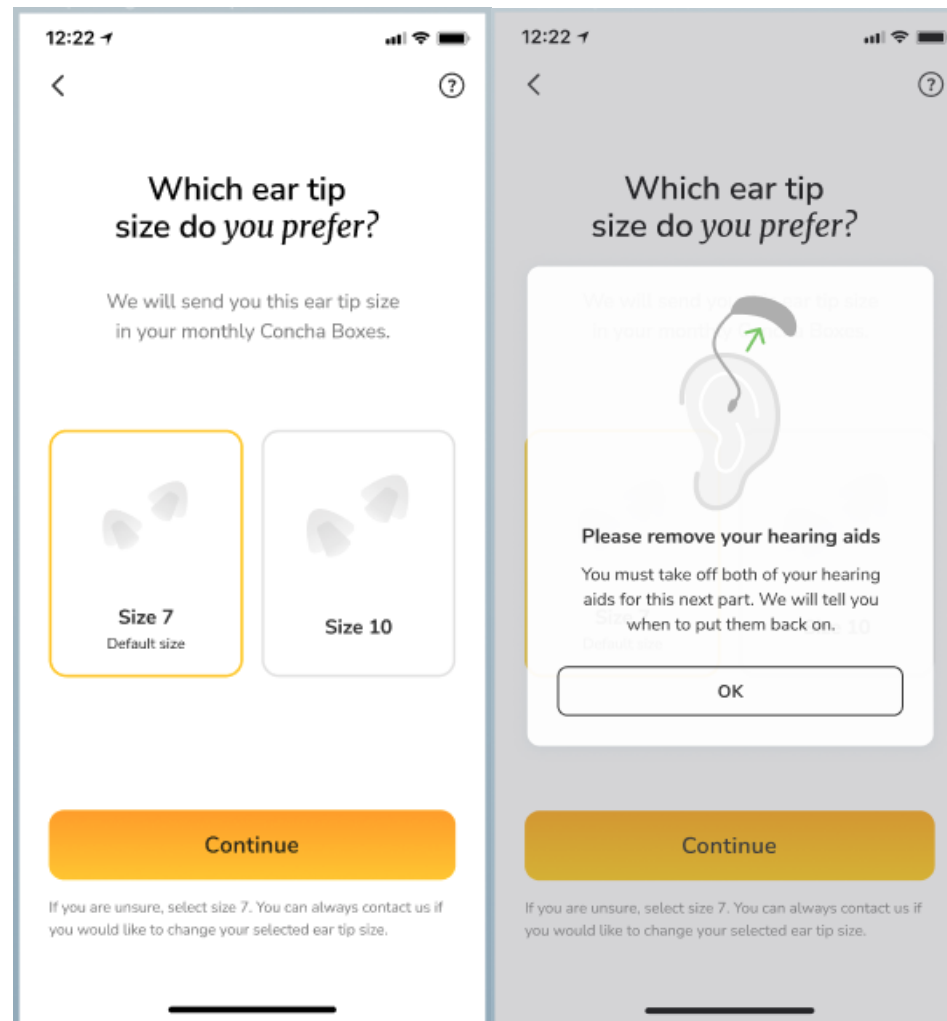


Figure 14: Ear tip size selection

7.3.4. Pairing the Hearing Aids with an iOS Smartphone

After ear tip size selection, the Concha Labs App will pair the hearing aids and get Bluetooth® set up. You must accept upcoming permissions as the app prompts you, in order to proceed. **The hearing aids should be removed from both ears for proper Bluetooth pairing.**

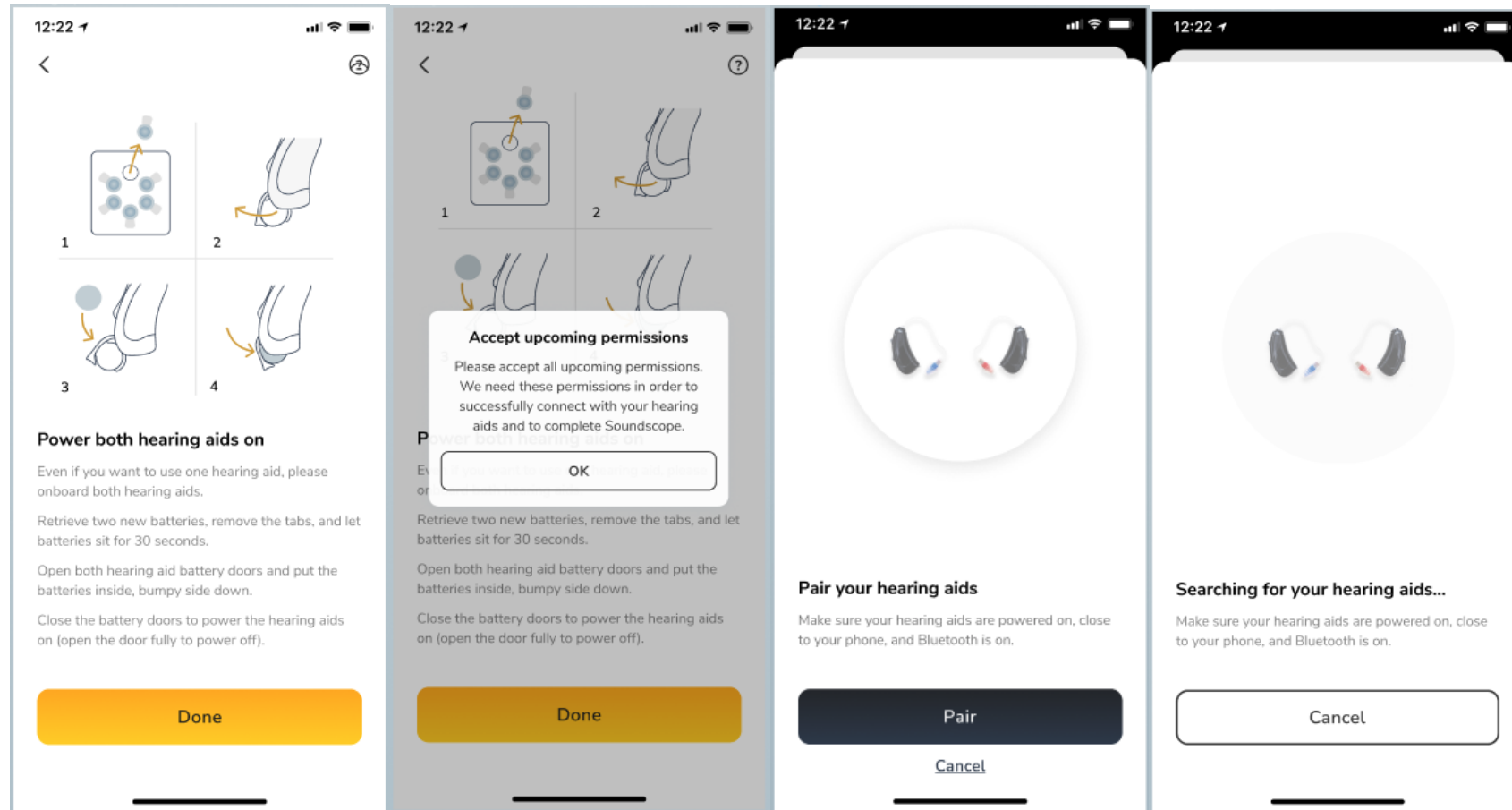


Figure 15: Pairing the Hearing Aids

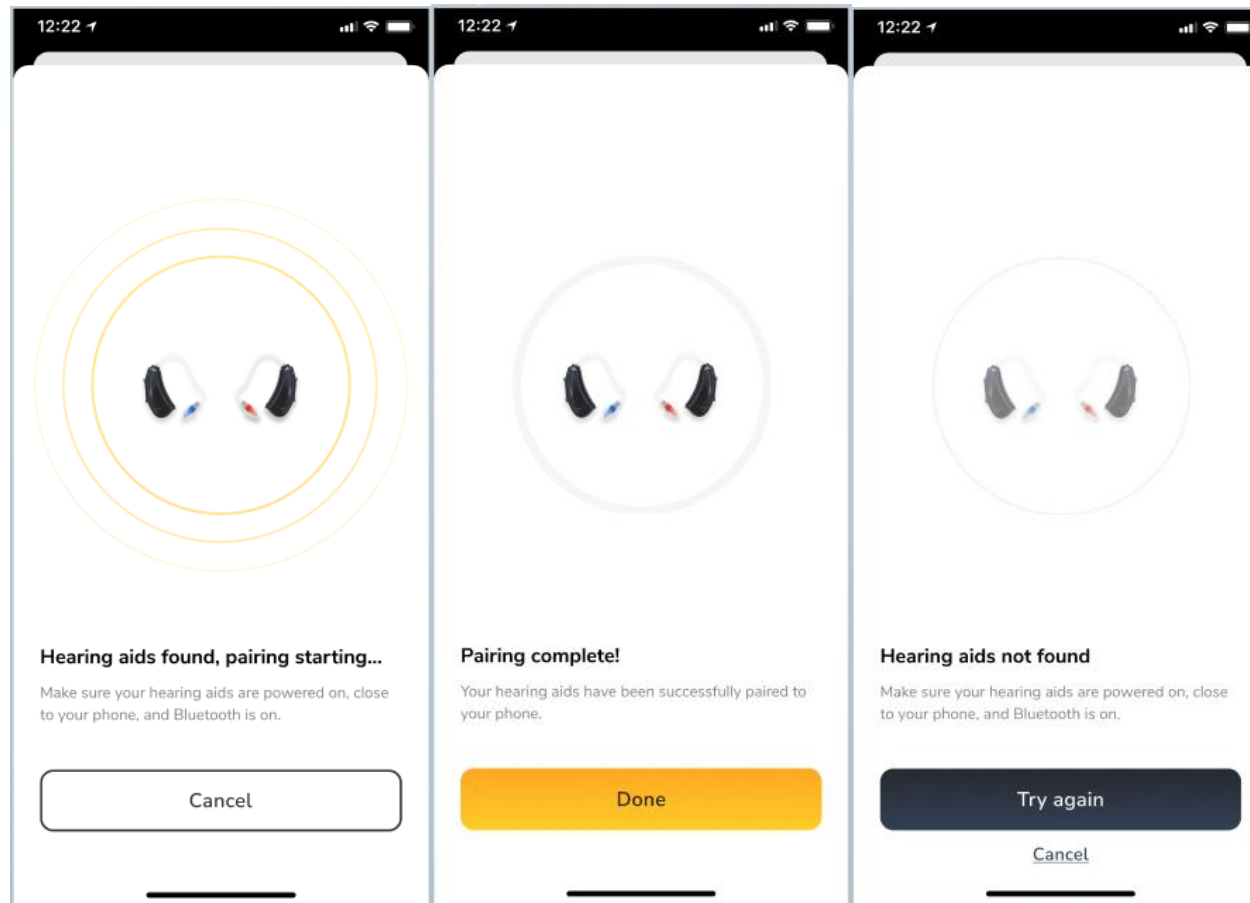


Figure 16: Pairing the Hearing Aids (continued)

Once the hearing aids are paired with the mobile phone, the Concha Labs App will configure them. Follow the steps in the app in order to complete the configuration. It is important to perform the configuration in a quiet environment. If the environment is not quiet, the app will indicate as such and ask you to move to a quieter location. Please accept any permissions the app prompts you on.

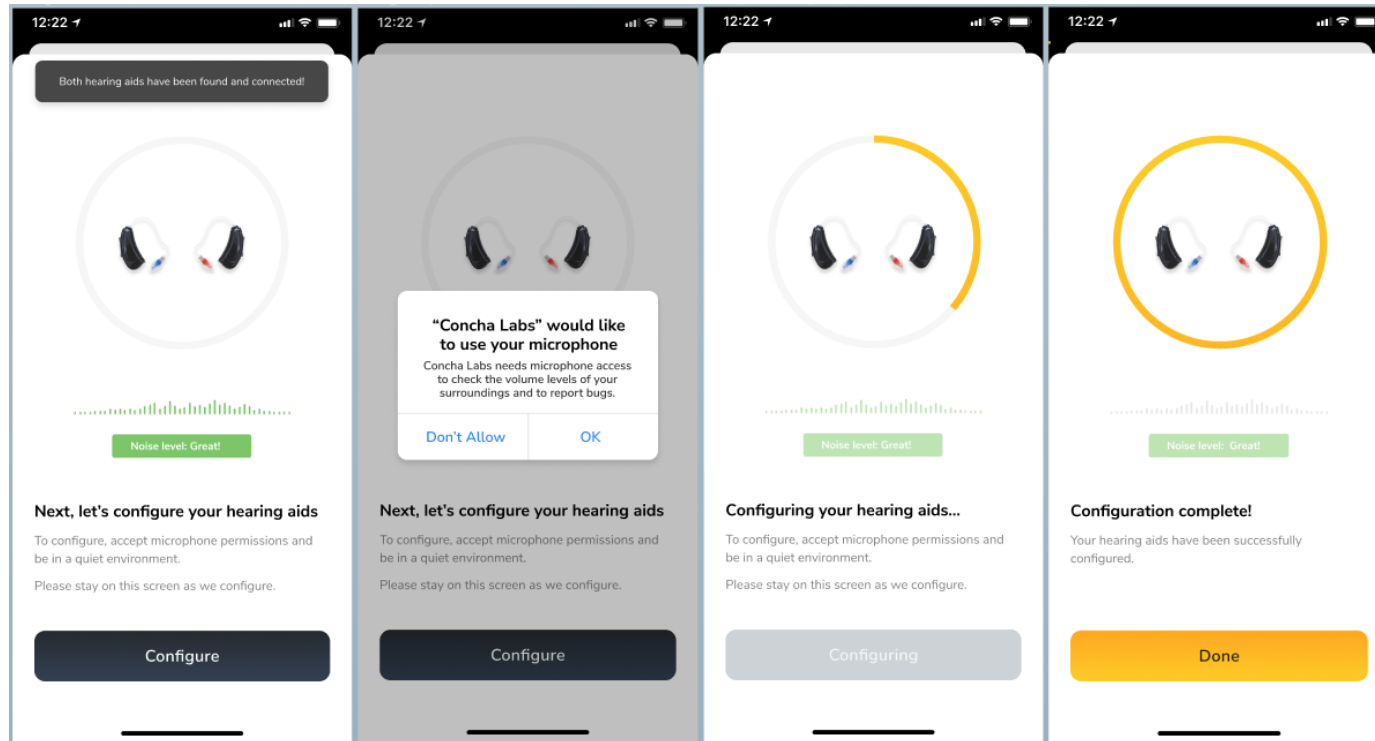


Figure 17: Hearing Aids Configuration

7.3.5. Setting Up Your First Sound Profile

Before starting the Soundscope profile creation process, ensure you are in a quiet room. Soundscope will ask a series of questions, starting from simple sounds and progressing to more granular and life-like sounds and speech, to personalize your sound profile. The Soundscope process is performed on one ear at a time. Please follow the directions and select choices that can provide you the most comfortable listening experience. If at any point you run into any difficulties, please tap the question mark icon on the upper right for troubleshooting information.

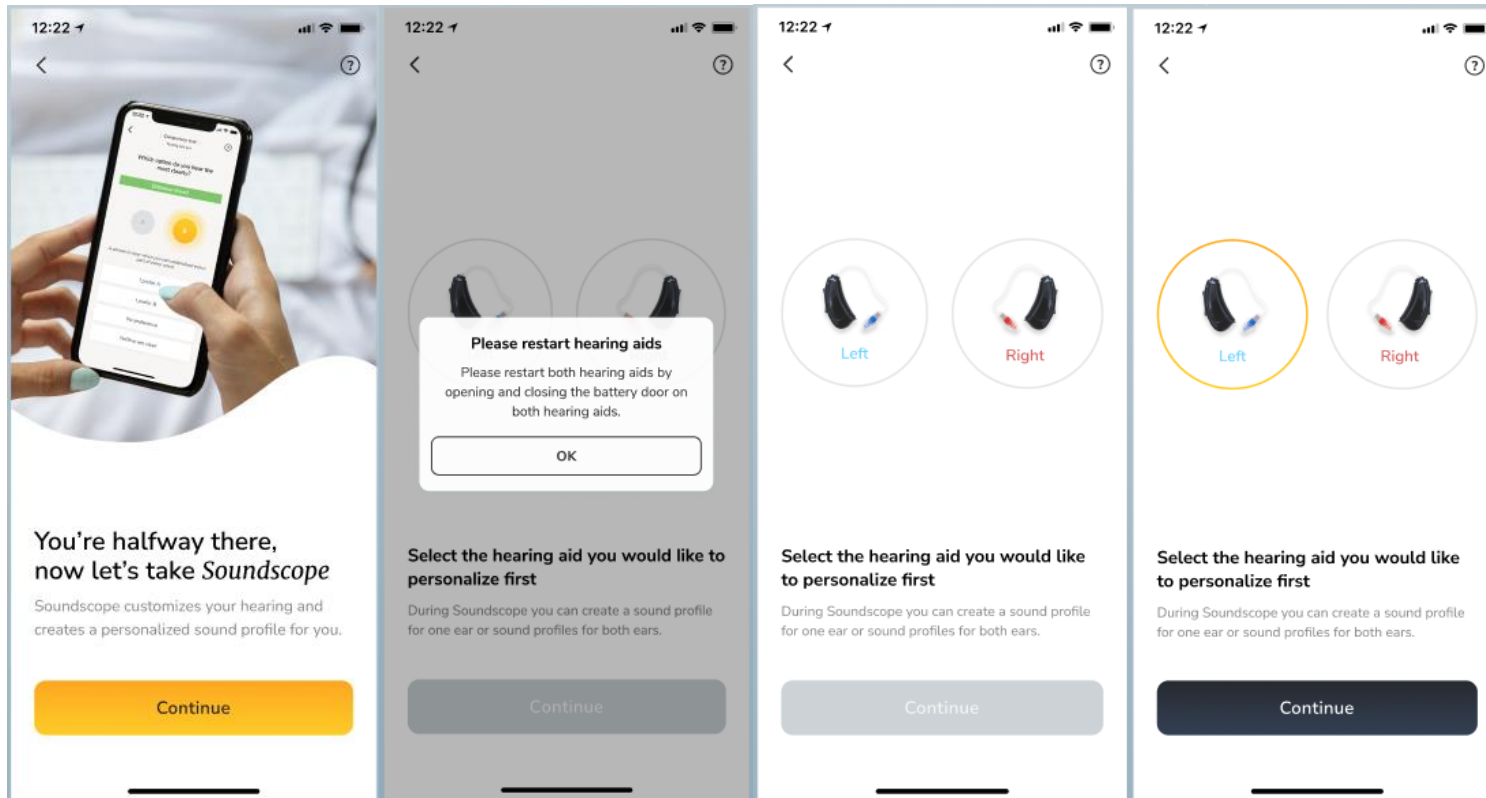


Figure 18: Beginning Soundscope

You may create a unique name for your Soundscope profile. The app will prompt you to enter the name.

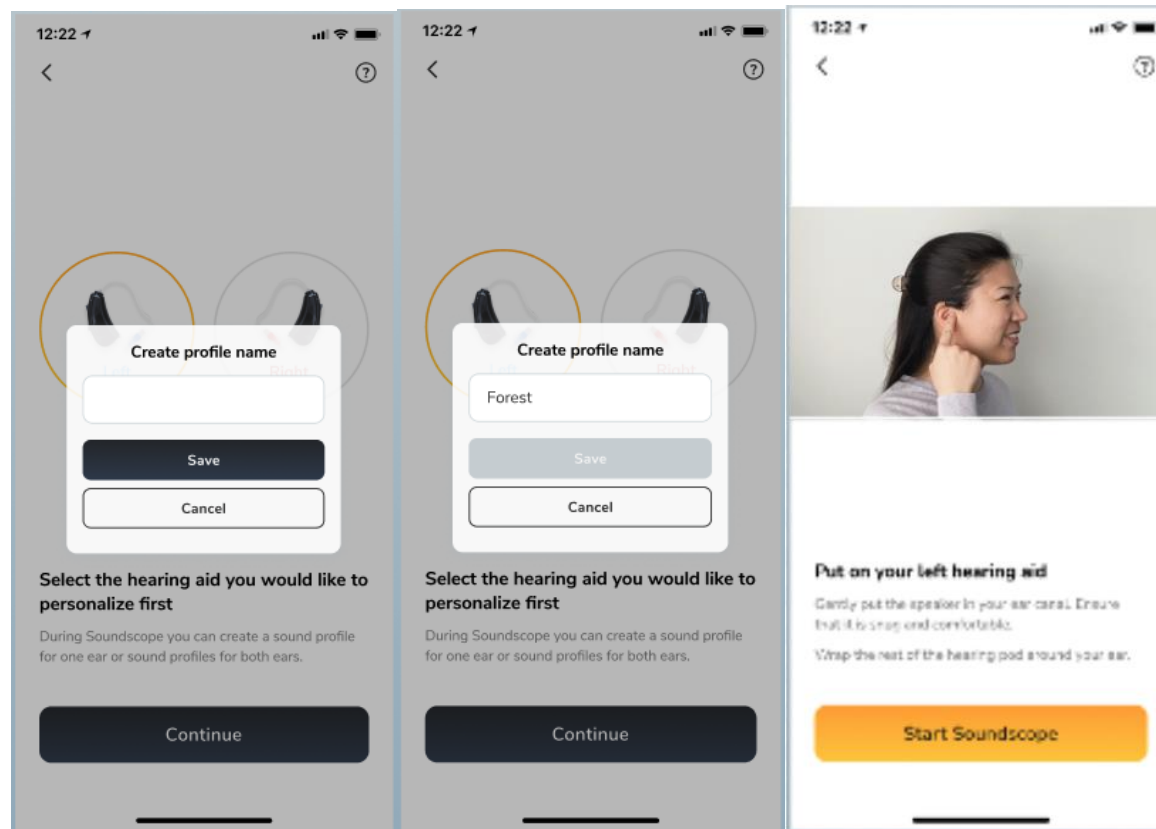


Figure 19: Naming Soundscope Profile

Soundscope will then start.

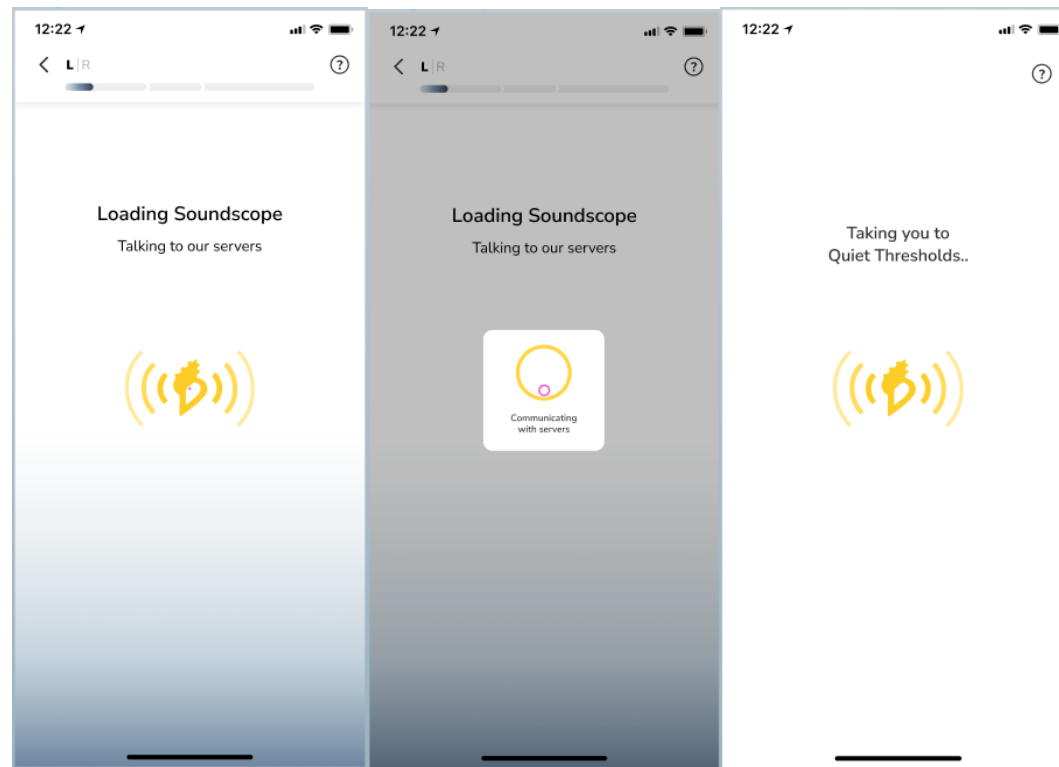



Figure 20: Starting Soundscope

Soundscope will ask a series of questions, starting from simple sounds and progressing to more granular and life-like sounds and speech, to personalize your sound profile. Please follow the directions and select choices that can provide you the most comfortable listening experience. Soundscope uses a combination of streaming directly to your hearing aids and playing from your smartphone speaker. When Soundscope begins, it may ask you to configure streaming sound to the hearing aid from your phone by displaying the Apple AirPlay  connection screen. If so, please select the Concha Sol Hearing Aids to proceed.

The first section of Soundscope, Quiet Thresholds, begins with instructions on preparing for the process.

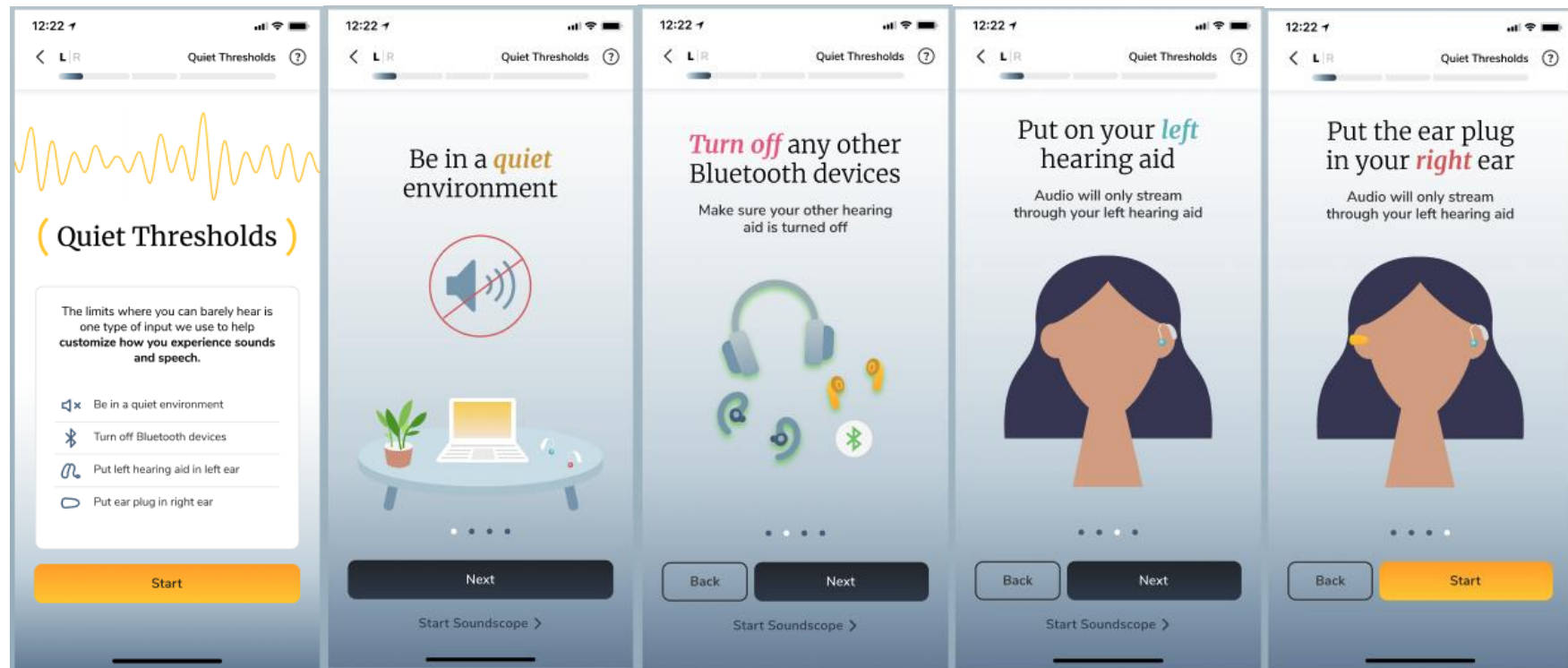


Figure 21: Quiet Thresholds

Soundscope will ask you to turn the master volume of your mobile phone to the highest setting for the duration of the process. Then a series of sounds will be played through the hearing aid and you will be asked to raise corresponding sliders to the levels at which you first hear the sounds.

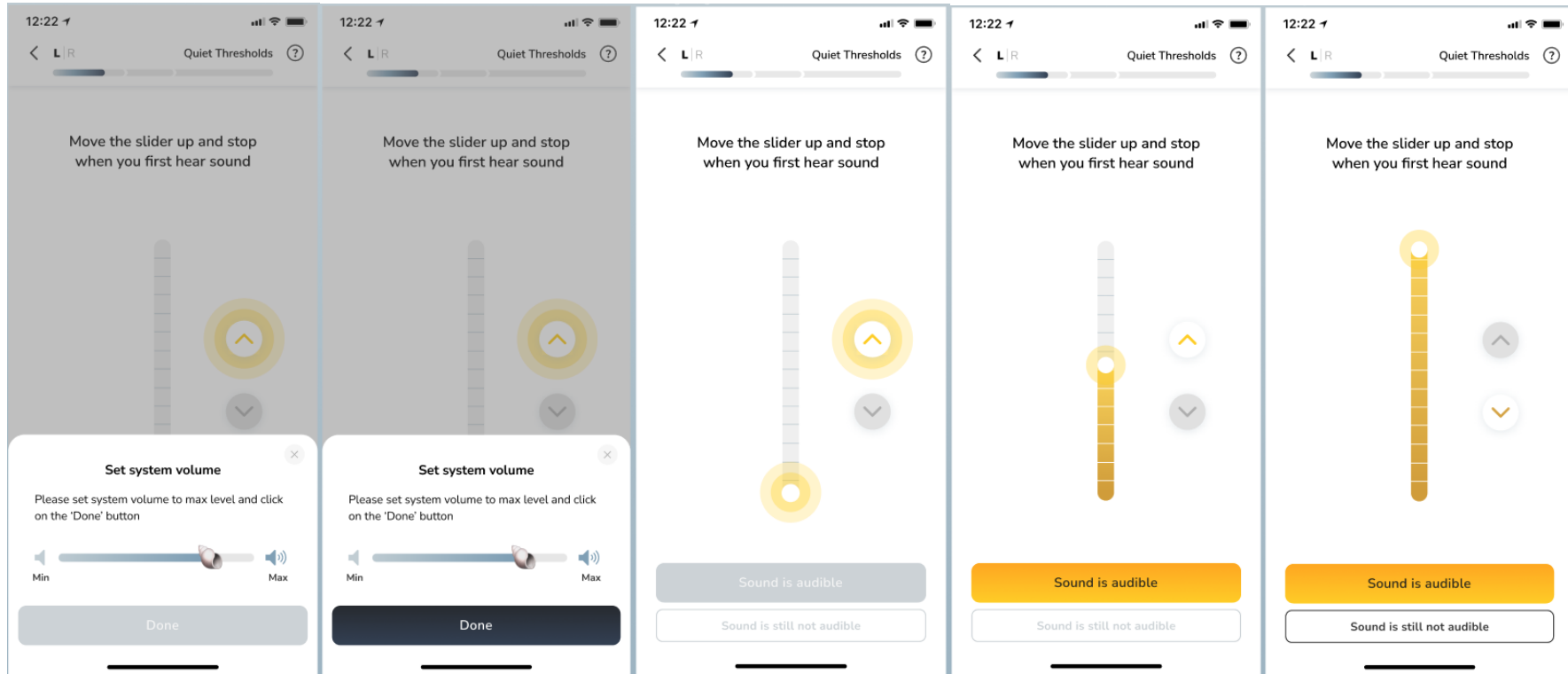


Figure 22: Quiet Thresholds (Continued)

The comfortable listening level section of Soundscope uses the camera on your smartphone to ensure that you are holding the phone in the correct location relative to your ears. You need to grant permission to the app to use it in order to proceed.

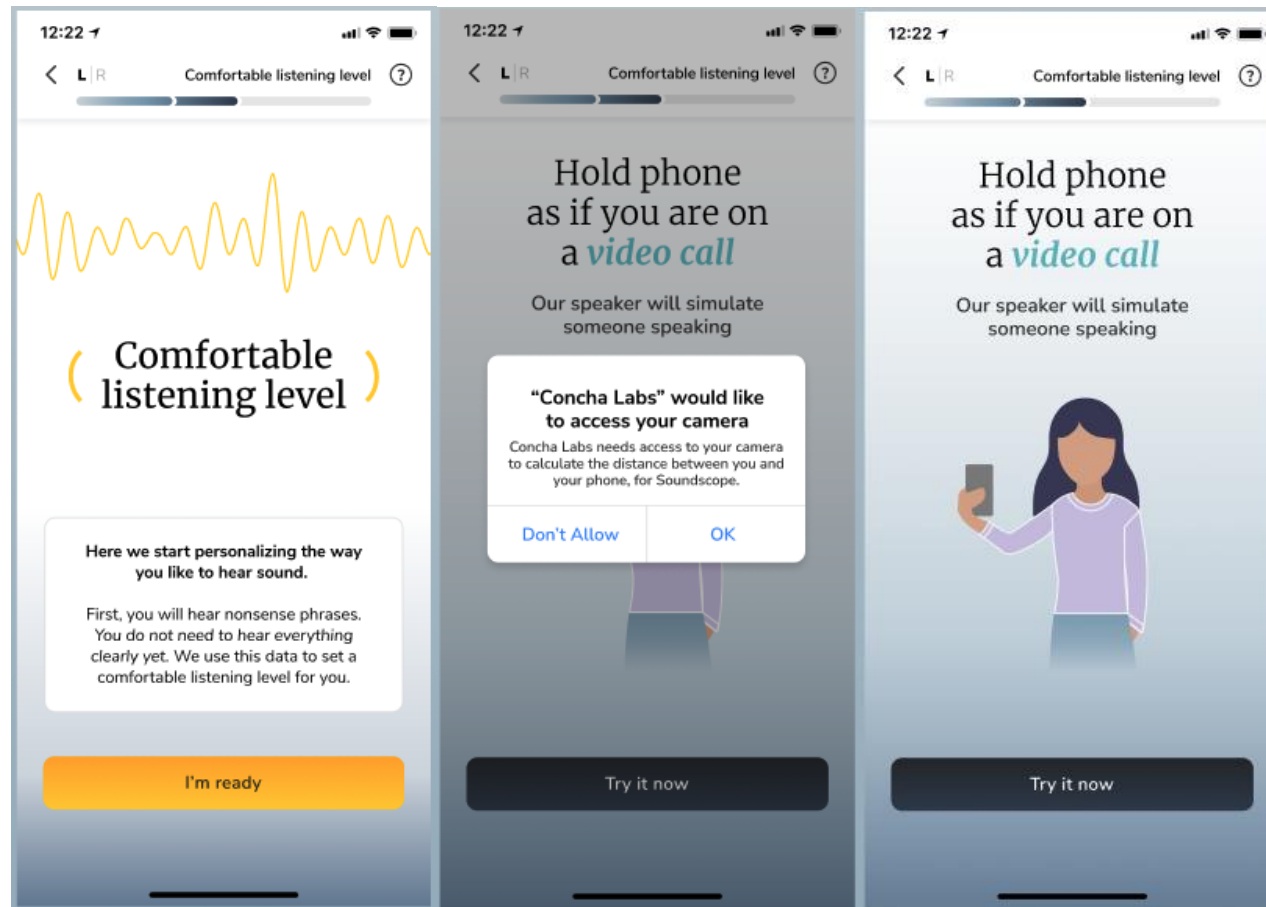


Figure 23: Comfortable Listening Level Permissions and Intro

For the remainder of Soundscope, sounds will be played from the mobile phone speakers. The phone must be held correctly in order to get the best results, so a short tutorial is provided. Hold the phone as if you are on a video call. When the border is red, the phone is incorrectly positioned. When it is green, it is correctly positioned and the app will proceed.

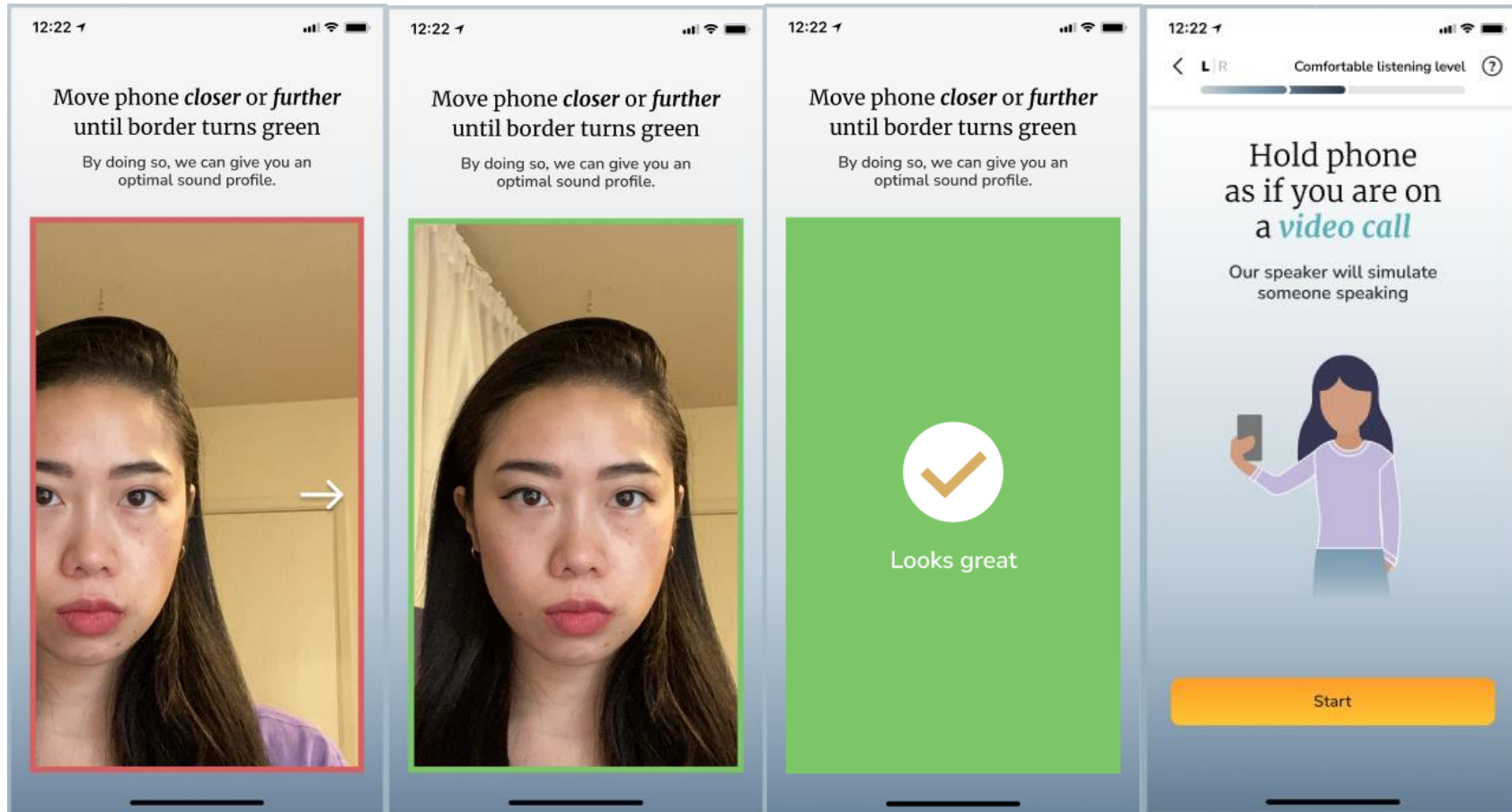


Figure 24: Phone Position Tutorial

With the phone being held correctly as in the tutorial. The screen will provide feedback on the phone position. Listen to the sound being played with the phone held in the correct position. If the sound level is incorrect you can raise or lower the overall level. You may not be able to understand everything clearly just yet. If the overall volume level is fine, select “This sounds great” and the app will proceed. There is a link provided at the bottom of the screen to reset the level if you have gotten off track!

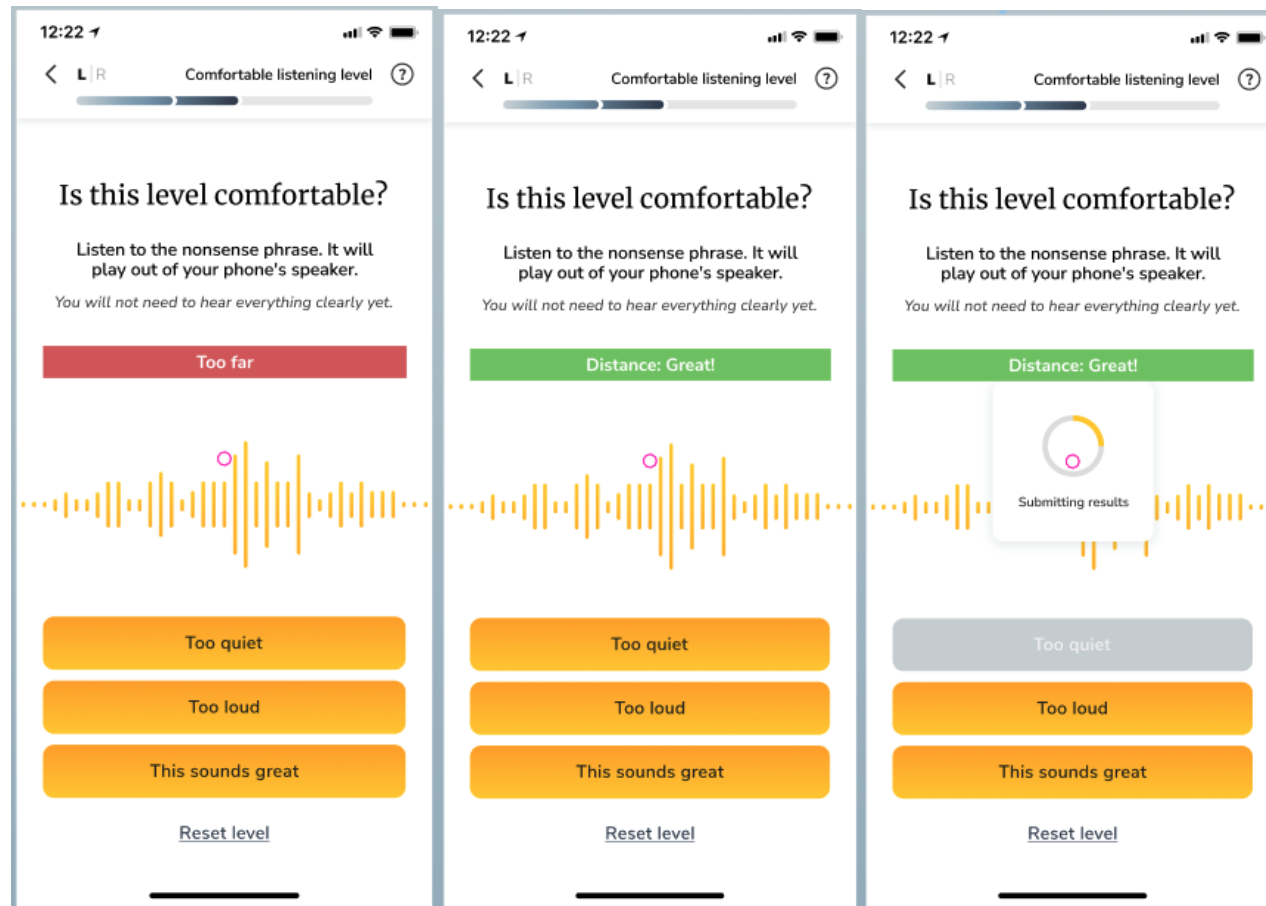


Figure 25: Comfortable Listening Level

Once the overall level of the device is acceptable, the app will play a series of sentences. Each sentence will be read twice – once with one set of hearing aid settings (A) and once with a second set of settings (B). Select whether A or B sounds clearer. If they both sound clear, select “No preference”. If neither do, select “Neither Are Clear”.

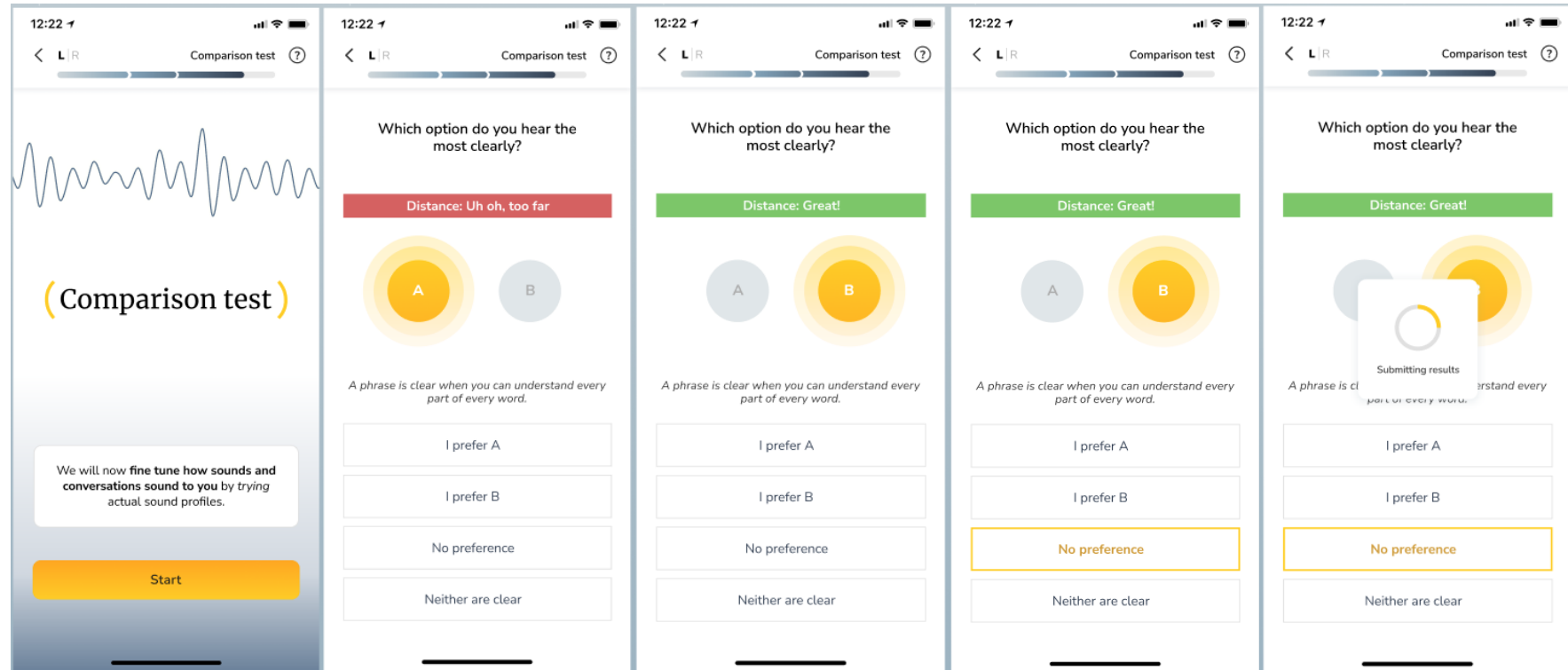


Figure 26: Comparison Test

After you create a sound profile for one ear, you can create a sound profile for your other ear.

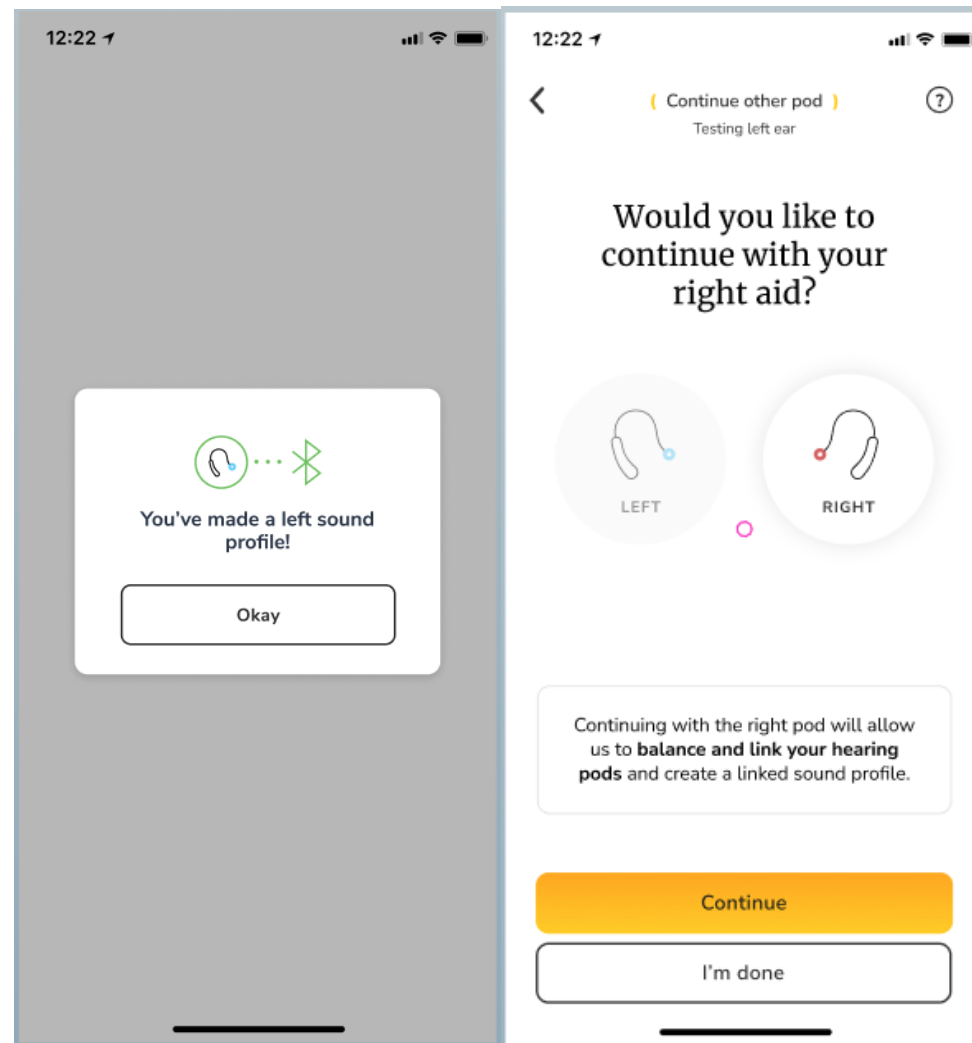


Figure 27: Second Hearing Aid

After you have successfully created sound profiles for both ears, if you perceive the sound profile to not be at the same loudness level across the left and right sides, you have the opportunity to balance the two sides. If you initially indicate that the levels of the hearing aids are matched, your left and right sound profiles are linked and automatically saved. If you indicate otherwise, then a pair of up and down arrows appear on the screen corresponding to the left and right hearing aids. Please adjust up or down and until you are happy with your adjustment.

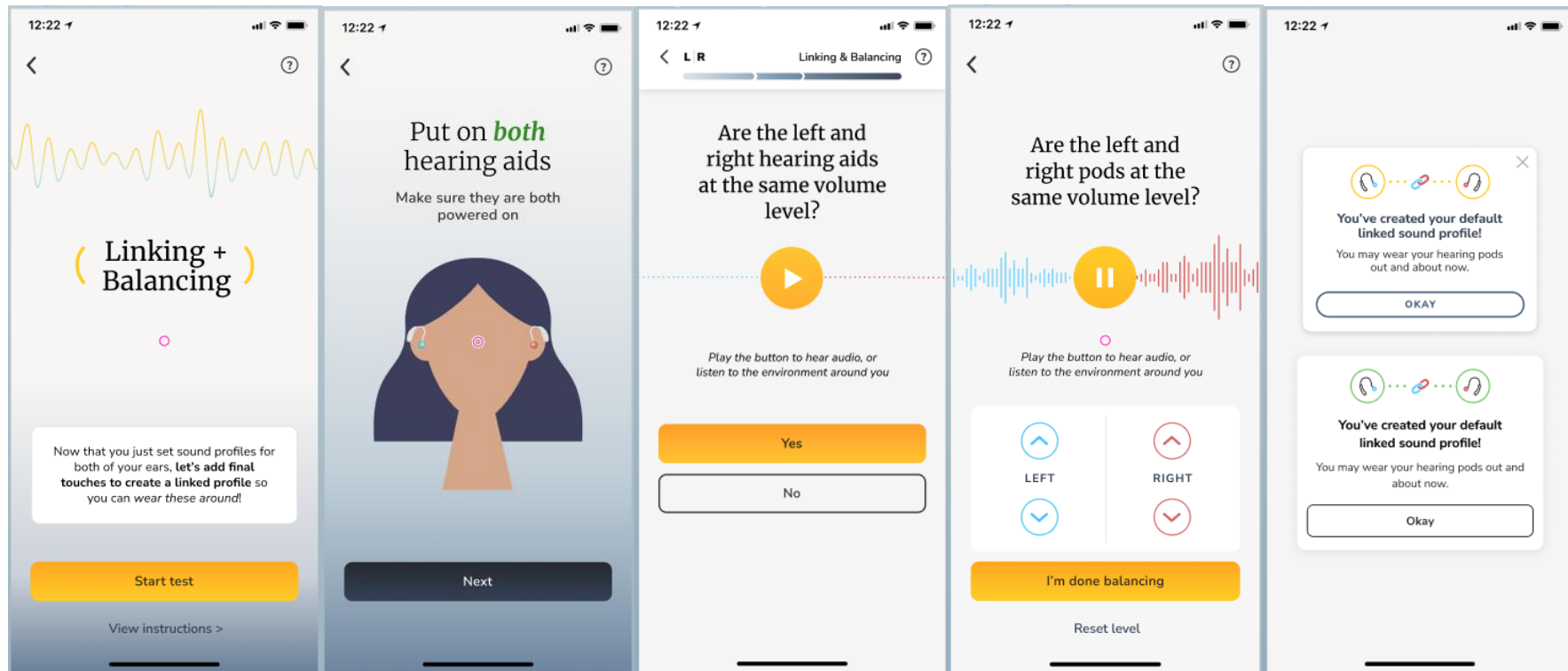


Figure 28: Linking and Balancing

Once you have gone through Soundscope with both hearing aids, the app will give you information about your results. You will be prompted to return the volume of your mobile phone to your typical level.

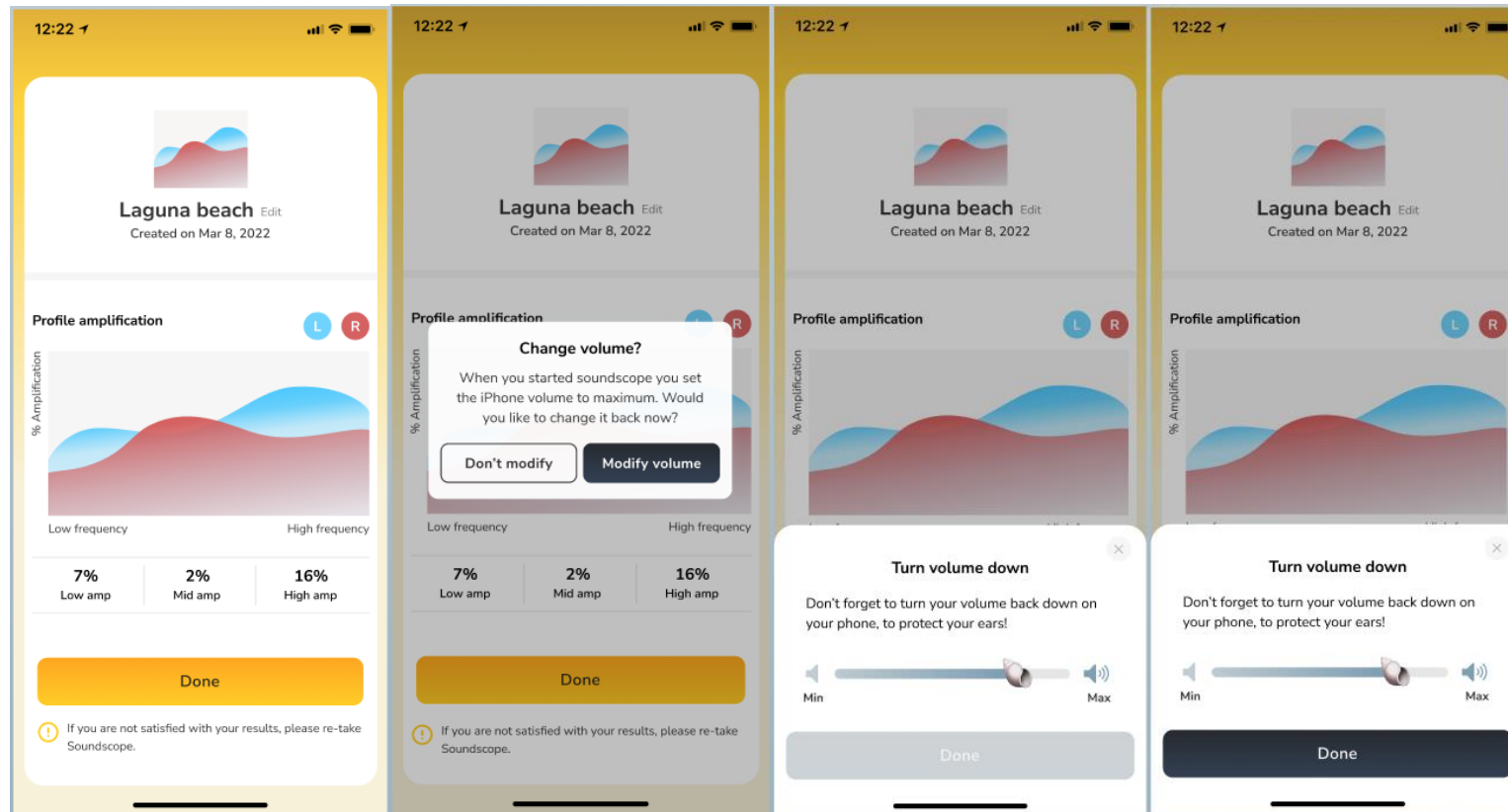


Figure 29: Soundscope Results

When the first sound profile has been created, two additional profiles are automatically generated as well. Noise Comfort and Streaming Comfort. Noise Comfort is optimized for listening to speech in noisy environments. Streaming Comfort is optimized for streaming audio from the phone directly to the hearing aids. You may want to increase the volume of your phone when using this profile. Selecting this profile will not automatically stream audio to the device. To do that, see [“Streaming Audio to the Hearing Aids”](#).

Your Concha Sol Hearing Aids are now set up for use!

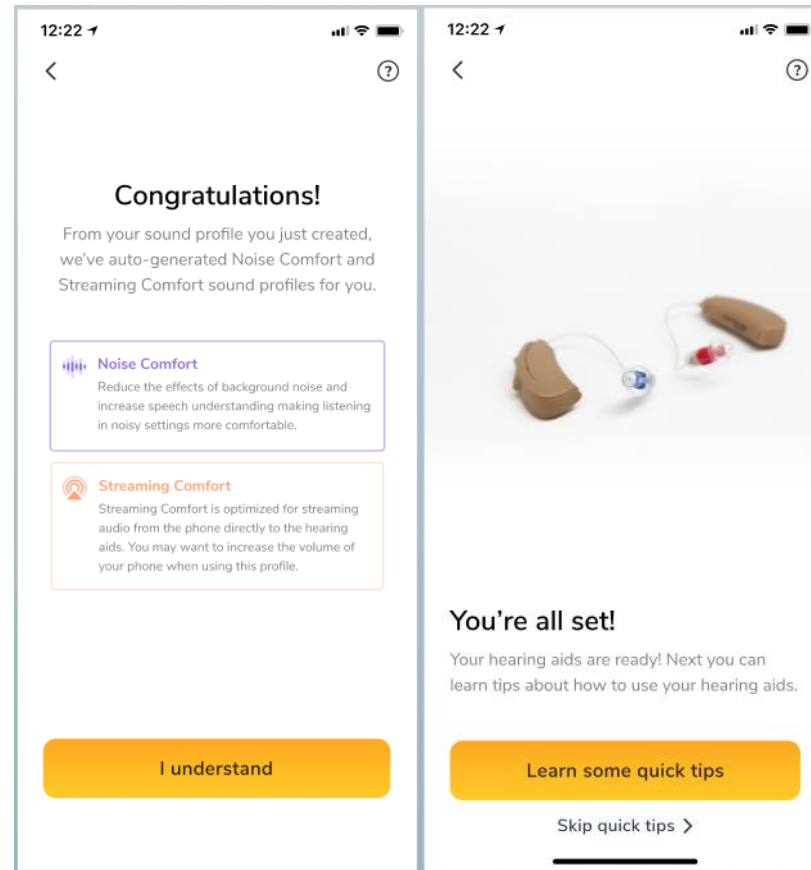


Figure 30: Setup Completed Screens

7.3.6. Hearing Aid Tips

The final step of onboarding is the option to view some Quick Tips about your Concha Sol Hearing Aids. After the quick tips or, if you decide to skip the quick tips, you will be given a short tour of the App and how to use it going forward.

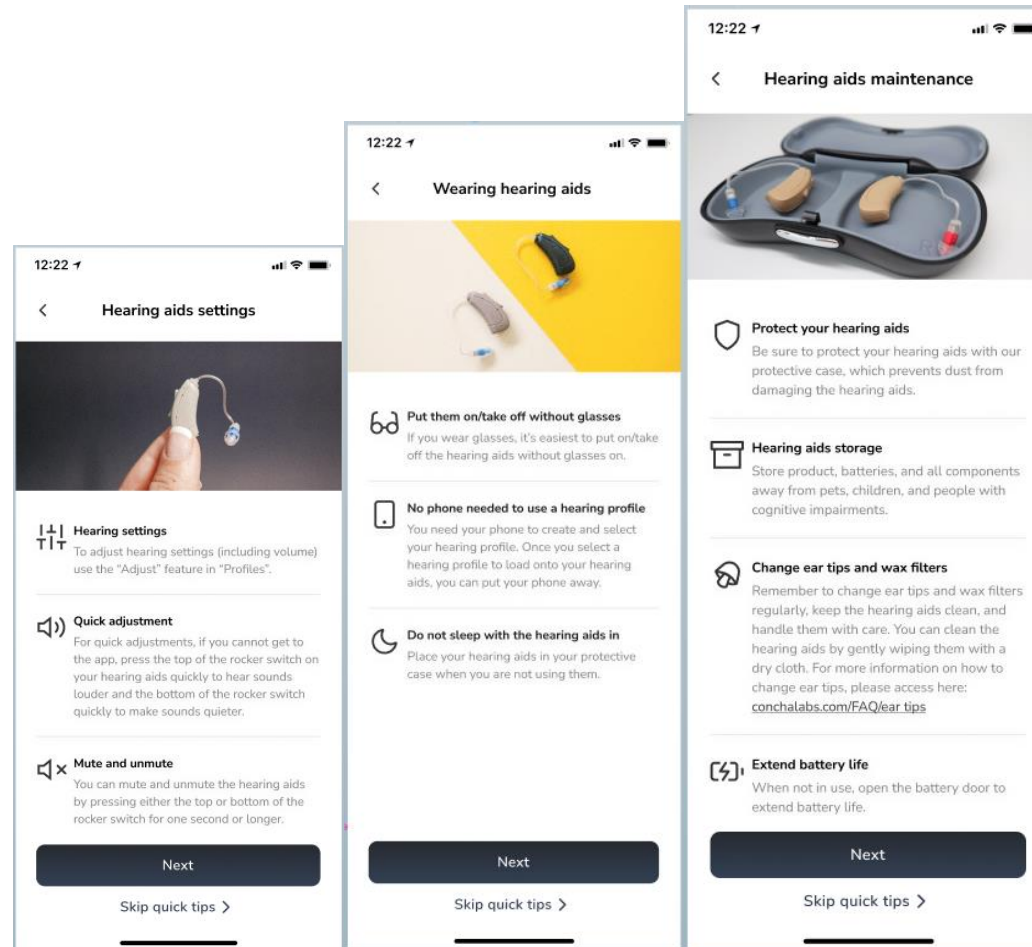


Figure 31: Hearing Aid Tips

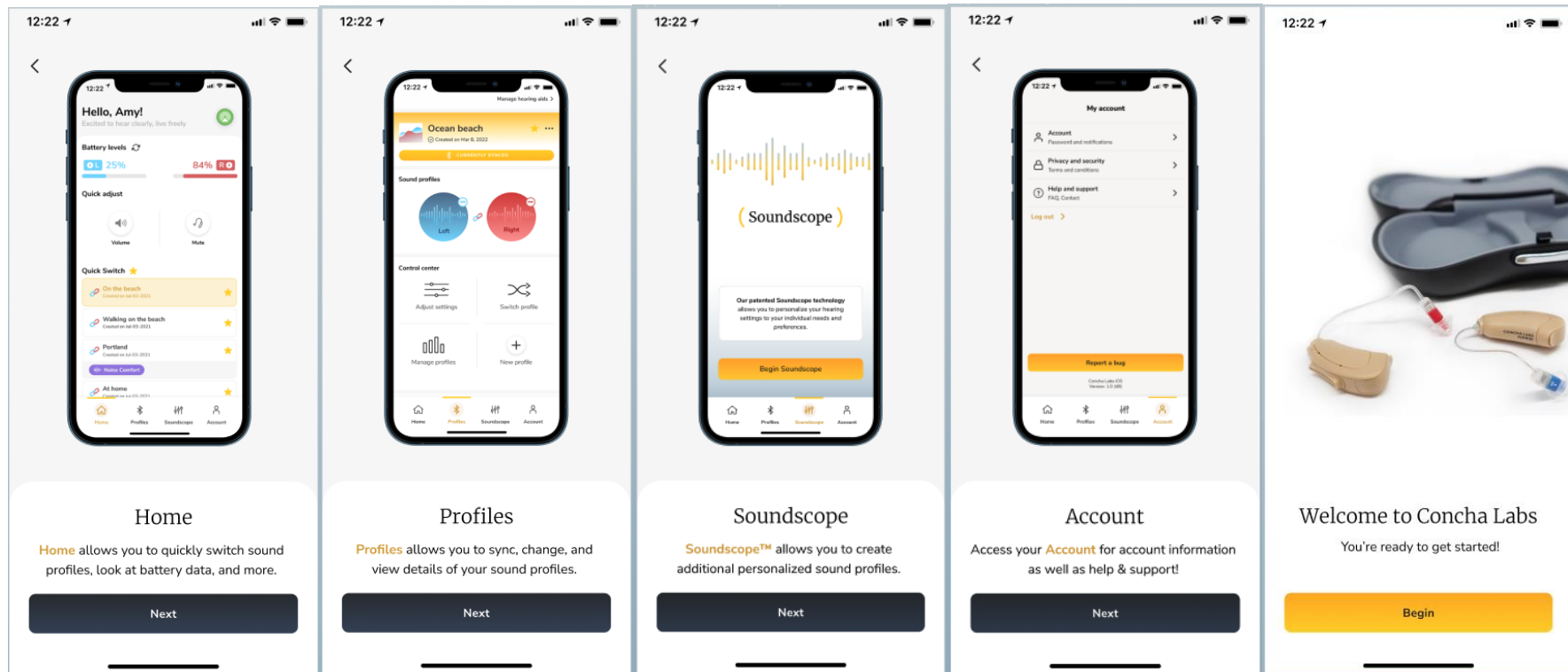


Figure 32: App Tutorial

8. Using the Concha Sol Hearing Aids

The Concha Sol Hearing Aids allow for multiple Soundscape profiles to be created. If you wish to create additional profiles, please follow the steps below.

Creating Additional Soundscape Profiles

Before starting the Soundscape profile creation process:

- Ensure you are in a quiet room.
- Ensure the hearing aids have been properly positioned in your ears using the correct ear tips.
- If you have never created your unique sound profile with your hearing aids, follow the setup instructions on the Concha Labs' mobile app and described in Section 7 to create your first sound profile.
- If you have already created your first sound profile, to create a new profile:
 - Open the Concha Labs' mobile app.
 - Click on "Soundscape" on the bottom navigation bar.
 - Tap on "Create New Profile".
 - Then select either the left or right hearing aid to begin.
 - On the next screen create a profile name by typing a name.
 - Then tap "Save" and on the next screen tap "Start Soundscape".
 - The screen will then display the message "Loading Soundscape".
 - Begin Soundscape and follow instructions found in Section 7.3.5 to create and customize your sound profile.
- If at any point you run into any difficulties, please tap the question mark icon on the upper right for troubleshooting information.

Adjust

- You can adjust existing sound profiles through the Concha Labs' mobile app. Navigate to the sound profile you want to adjust on the Profiles tab to view details and tap "Adjust settings".
- To quickly and temporarily increase or decrease the level of your surroundings without modifying the saved sound profile, select "Volume" on the Home tab of the application.

Rocker Switch

- The Concha Labs' mobile app provides the preferred way of increasing or decreasing the level of your surroundings (See "[Adjust](#)"). If you do not have easy access to the Concha Labs' mobile app, you may raise the volume by quickly pressing the top of the rocker switch on the device (less than half a second press), and lower the volume by quickly pressing the bottom of the rocker switch (less than half a second press).
- You can mute and unmute the hearing aid by pressing either the top or bottom of the rocker switch for one second or longer.

Manage

- You can manage your sound profiles by renaming or deleting your sound profiles within the mobile app. You can indicate your favorite sound profiles by marking the star next to the profile name.
- To rename a profile:
 - Select the “Profiles” tab
 - Tap “Manage Profiles”
 - Tap on the three dots of the sound profile you want to rename, then select “View Sound Profile”
 - Tap on the three dots, then select “Edit profile name”
 - Type in the new name for the profile
 - Click “Save”
- To delete a profile:
 - Ensure you are not syncing the sound profile you want to delete
 - Select the Profiles tab
 - Tap “Manage Profiles”
 - Select the profile to delete
 - Tap on the three dots, then select “View Profile”
 - Select “Sound Profiles-edit”
 - Tap (-) on the L Profile
 - Tap “Yes, Delete”
 - Tap (-) on the R Profile
 - Tap “Yes, Delete”

Using Comfort Profiles

- The first time you create a sound profile by taking Soundscope, Comfort Profiles are auto-generated for you.
- When creating additional sound profiles by retaking Soundscope, you will be given the option to auto-generate Comfort Profiles based upon the new sound profile you just created.
- There are currently two Comfort Profiles:
 - Noise Comfort is optimized for listening to speech in noisy environments.
 - Streaming Comfort is optimized for streaming audio from the phone directly to the hearing aids. You may want to increase the volume of your phone when using this profile. Selecting this profile will not automatically stream audio to the device. To do that, see [“Streaming Audio to the Hearing Aids”](#)

Streaming Audio to the Hearing Aids

It is possible for sound from your phone to be streamed directly to the Concha Sol Hearing Aids. To do so:

- Power on the hearing aids.
- Swipe down on the upper right corner of the iPhone.
- Click on the upper right icon in the “Now Playing” box.
- Select the “hearing device” icon (assuming your hearing aids are on).

We recommend using the Streaming Comfort sound profile while streaming audio directly to the hearing aids. See [“Using Comfort Profiles”](#).

Using the App Offline

Some features of the Concha Labs mobile app are still available for use when your phone is not connected to the internet, others are not.

- Features that are still available when the app is not connected to the internet:
 - Connecting to the hearing aids.
 - Viewing battery levels.
 - Streaming audio to your hearing aids from your phone.
 - Muting and unmuting the hearing aids.
 - Adjusting the hearing aid volume (note that changes will not be saved to your profile).
 - Switching to other sound profiles.
- Features that require the app to be connected to the internet in order for them to be used:
 - Logging in to the app.
 - Taking Soundscope to create a new profile.
 - Creating Comfort Profiles.
 - Deleting existing sound profiles.
 - Links to the Concha Labs website.
 - Changing your password.
 - Selecting a profile as a Favorite.
 - Editing a profile name.
 - Adjusting a profile.
 - Reporting a bug.

Changing Account Password

If you would like to change your account password, you may do so in the Account Settings of the Concha Labs App. Click on the “Account” tab at the bottom of the screen, then click on “Account” > “Password”. Enter the new password information and then click on “Update password”. Passwords must have:

- Minimum of 8 characters
- At least one capital letter
- At least one symbol (!@#%&*()_-+={}|?>.<,:;~`')

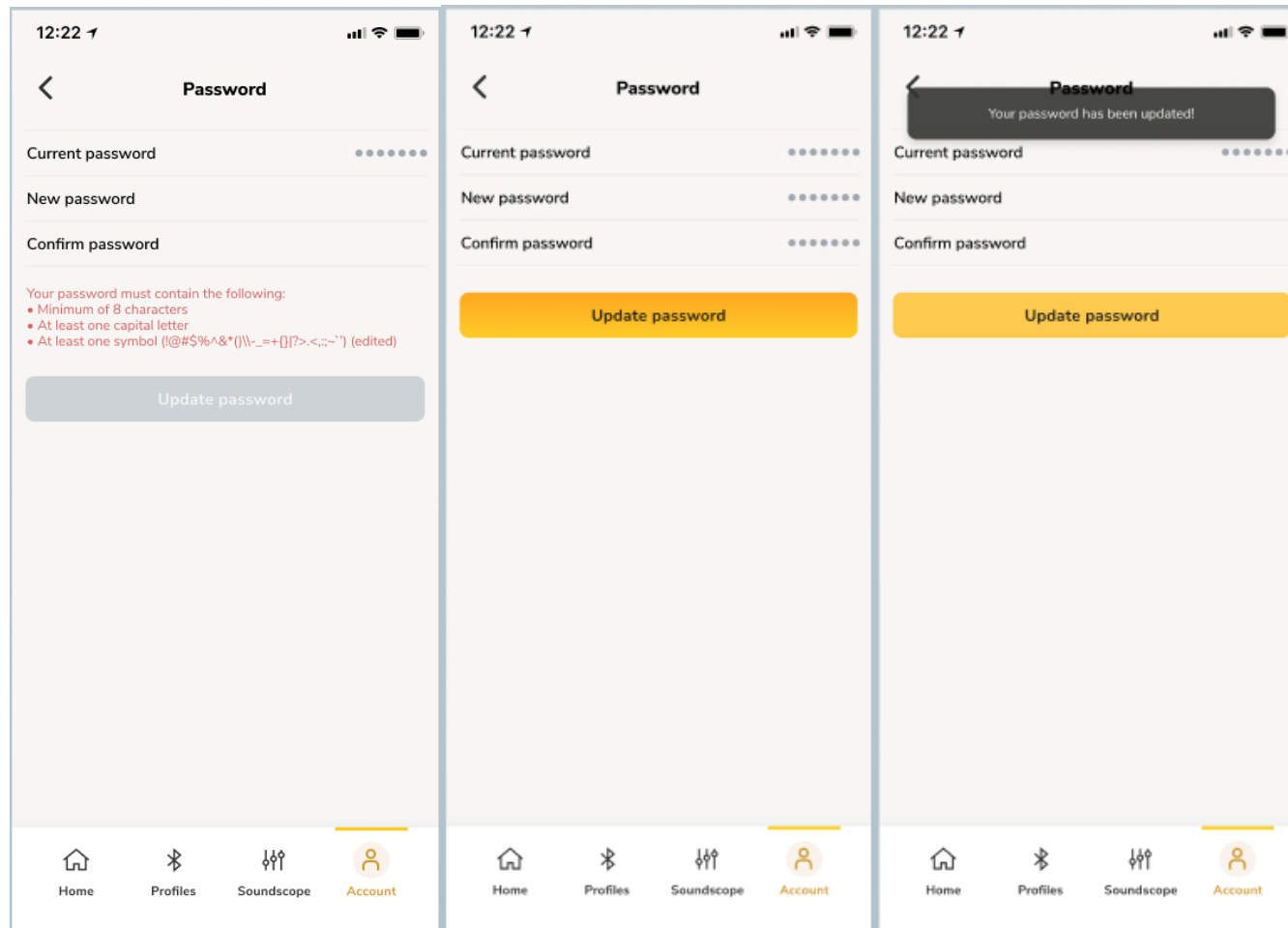


Figure 32: Changing Account Password

9. Care and Maintenance

Battery Information



- Concha Sol Hearing Aids use type Zinc Air batteries size 312.
- Batteries in this product are replaceable. See below.
- The hearing aids battery operating life is approximately 5-7 days based on average use.
- If abused or misused, the batteries may leak and may cause chemical burns.

Changing the batteries

- When the Concha Labs App displays a battery level of 10% or less, or when the low battery alert sounds in your ear, the batteries should be replaced.
- Remove the 312 Zinc Air battery from the packaging. Remove the tab from the battery.
- Open the 312 Zinc Air battery compartment with your finger at the edge and swing it out.
- Insert the battery in the battery compartment. Ensure the (+) symbol on the battery is facing you when inserting the battery.

Note: Do not force the battery into the battery compartment. If it does not fit, check whether you are inserting it correctly and that the battery is the correct size.

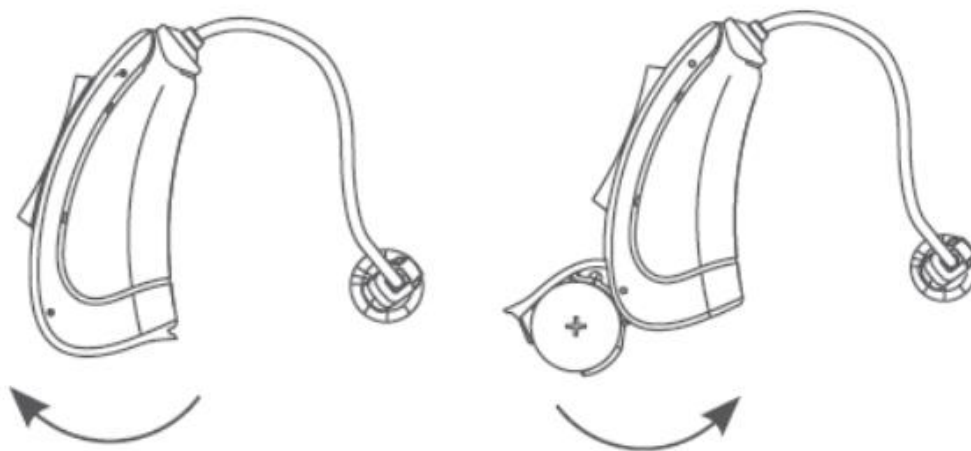


Figure 33: Battery Installation

Caring for the Hearing Aids

Important Note: We do not recommend using alcohol wipes when caring for your hearing aids.

Hearing Aids General Maintenance

- Ear Tips
 - The user should verify accurate fit to determine the most suitable size for their needs. A secure fit is essential for proper operation.

- The Concha Sol is shipped with the medium (7mm) ear tips in place. The hearing aids come with an additional pair of 7mm ear tips and two pairs of 10mm ear tips. Pick the largest size ear tip that fits comfortably in your ear and forms the best seal. If it feels like the device is falling out of your ear, the ear tip is likely too small for your ear. If it feels like you have to force the device in your ear, the ear tip is likely too large.
- To replace ear tips:
 - Holding on to the speaker with one hand, pinch the ear tip with the other hand and wiggle the ear tip off of the speaker. Discard the used ear tip.
 - Line up the base of the new ear tip with the speaker and push the tip onto the speaker. Ensure that the ear tip is snug by pushing the ear tip firmly onto the speaker.



- Hearing aids are designed to be worn with ear tips attached. Do not attempt to insert the hearing aids into your ears without ear tips attached.

➤ Ear Wax Filters

The devices have an ear wax filter to prevent ear wax from entering and clogging your hearing aids. This filter must be changed periodically. To change the ear wax filter in your Concha Sol Hearing Aid:

- Remove the ear tip from the receiver following the instructions above.
 - Remove a new wax filter and tool from the package. One end of the tool is for removing the old filter, and the other contains the new filter to insert.
 - Insert the empty end of the tool into the tip of the receiver to gently pull the dirty wax filter loose from the unit.
 - Using the other end of the tool, gently install the new filter.
 - Discard the tool containing the dirty filter.
- Follow the steps under the General Information section below to help maintain audio quality of your hearing aids.

General Information:

- Protect your hearing aids against moisture (e.g. showers, rain), and take your hearing aids out before using hairspray or similar cosmetic products.
- Your hearing aids can be worn when sweating; however, excessive sweating may damage your hearing aid in the long term unless dried on a daily basis. We recommend carrying out daily care on them as these devices are exposed to moisture and dust through intended use, even when handled with care.
- Wearing a hearing aid or insertion of the ear tip in the ear canal may result in ear wax collecting on the ear tip. For this reason, we recommend regular care. Do not use a damp cloth to care for your hearing aids. Always use a soft, dry cloth.
- Should your hearing aid still not function correctly despite regular care, contact Concha Labs at care@conchalabs.com. Do not try under any circumstances to repair your hearing aid yourself.
- The product should not be discarded as household waste and should be delivered to an appropriate collection facility for recycling. Batteries should be disposed of according to local regulations and guidelines.
- The serial numbers for the hearing aids may be found inside the battery door of the devices.

Updating the Concha Labs App

If Background App Refresh is enabled on your iPhone, the Concha Labs App will update automatically when a new version is released with new features, cybersecurity measures, or bug fixes. This feature is typically on by default, but to check or to turn it on, go to Settings > General > Background App Refresh.

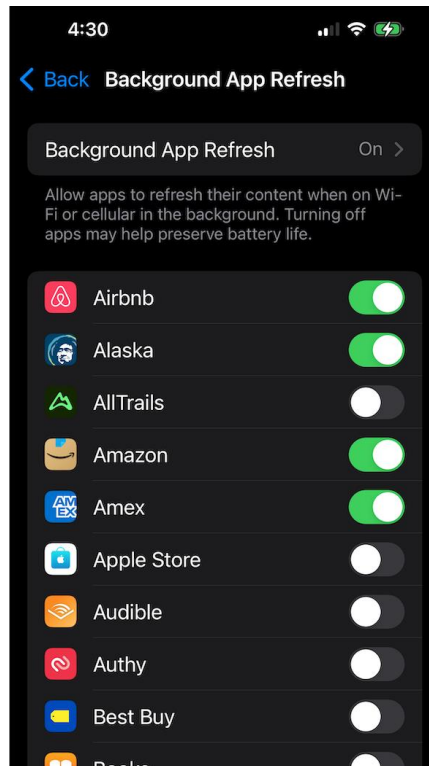


Figure 31: Background App Refresh

If you do not have Background App Refresh on, updates may be downloaded manually by going to the Apple Store from your phone, searching for the Concha Labs App, and clicking on the “Update” button. If your Concha Labs App is already up to date, an “Open” button will appear instead.

There may be times when the system parameters on your Concha Sol Hearing Aids may need to be updated. If that is the case, a notification about the necessary configuration update will appear on the screen when you open the Concha Labs Mobile App. Follow the instructions on the screen to allow the hearing aids to be reconfigured. Your hearing aids will temporarily stop amplifying while being configured. Upon completion, your sound profile will be restored, and the hearing aids will return to full functionality.

Replacement Components

Where can I buy additional components?

- Replacement components (e.g. ear tips, wax filters, batteries) can be purchased from Concha Labs. Please visit our website or contact us at care@conchalabs.com.

Privacy

- To view the Concha Labs privacy policy visit www.conchalabs.com/privacy/.

10. Troubleshooting

Common Solutions for Hearing Aids:

Symptom	Solution
Hearing aid doesn't power on	<ul style="list-style-type: none"> Check or replace the hearing aid batteries.
Hearing aid doesn't pair with cell phone (See "Bluetooth® Setup")	<p>Troubleshooting steps</p> <ol style="list-style-type: none"> 1. Reboot Your Hearing Aid Open and close the hearing aid battery. This will turn pairing mode off and back on and most likely will solve the problem. 2. Turn Your Phone Off And Back On Again Turning your iPhone off and back on is a simple troubleshooting step that can fix minor software glitches, which could be the reason why your hearing aid won't connect to Bluetooth®. 3. Turn Bluetooth® Off And Back On Again Turning Bluetooth® off and back on again can sometimes fix minor software glitches that may be preventing your hearing aid from pairing with your phone. There are two ways to turn Bluetooth® off and back on again on your iPhone: <p>Turn Bluetooth® Off in the Settings App</p> <ul style="list-style-type: none"> Open Settings. Tap "Bluetooth®". Tap the switch next to Bluetooth®. You'll know Bluetooth® is off when the switch is gray. Tap the switch again to turn Bluetooth® back on. You'll know Bluetooth® is on when the switch is green. <p>Turn Bluetooth® Off in Control Center</p> <ul style="list-style-type: none"> Swipe down from the top right of the screen of your iPhone to open the Control Center. Tap the Bluetooth® icon, which looks like a "B." You'll know Bluetooth® is off when the icon is black inside of a gray circle. Tap the Bluetooth® icon again to turn Bluetooth® back on. You'll know Bluetooth® is on when the icon is white inside of a blue circle. 4. Forget the Hearing Aid When you forget your hearing aid, it's as if the device was never connected to your iPhone. Next time you pair the devices, it will be like they are connecting for the very first time. To forget your hearing aid device: <ul style="list-style-type: none"> Open Settings. Tap "Bluetooth®". Tap the blue "i" next to the device ConchaLabs ZXXXXX . Tap "Forget This Device". When prompted again, tap "Forget Device".

Symptom	Solution
	<ul style="list-style-type: none"> You'll know the hearing aid has been forgotten when it no longer appears under My Devices in Settings-> Bluetooth®. <p>Once you've forgotten the hearing aid, reconnect it to your iPhone by power cycling the hearing aid. To do this simply open and close the hearing aid battery. If it pairs to your iPhone and starts working again, then your problem is solved. If you're still having problems, please move onto the next step.</p> <p>5. Disable MFI hearing devices pairing</p> <ul style="list-style-type: none"> Open Settings. Make sure Bluetooth® is on, then scroll down to Accessibility. On the Accessibility screen, scroll down and locate the field Hearing Devices. Tap on the MFI hearing devices that appear and choose Forget this device. Tap "Settings" (or "Confirm").
No sound when playing audio from cell phone	<ul style="list-style-type: none"> Check the hearing aid battery. Replace the hearing aid batteries if required. Increase the volume on your hearing aid and/or device. Make sure you are using the correct device paired to your hearing aids. Move your device closer to the hearing aids and away from any interference or obstruction. Ensure the connected mobile device is within range of the hearing aid (32 feet or 10 meters). Use a different music source.

Other Troubleshooting Tips

Symptom	Solution
Poor sound quality when playing audio from device	<ul style="list-style-type: none"> Pair a different cell phone (see "App Setup & Bluetooth® Pairing"). Disconnect the second device. Move the cell phone closer to the hearing aids and away from interference or obstructions. Clear any debris or wax from the hearing aid ear tips.
Hearing aid tips falling off	<ul style="list-style-type: none"> Securely attach the tips to the hearing aids.

Symptom	Solution
Lost hearing aid ear tips	<ul style="list-style-type: none"> Contact care@conchalabs.com to order replacement ear tips from Concha Labs.
Hearing aids whistle or create feedback	<ul style="list-style-type: none"> Through Concha Labs' mobile app, there may be options to reduce feedback and one way is to decrease volume through Adjust (see "Adjust").
Sound of own voice is too loud	<ul style="list-style-type: none"> You may go through the Concha Labs' mobile app to make adjustments (see "Adjust"). Also, practice listening to new sounds and talking on your own or with a trusted partner in a familiar environment.
App hangs or crashes	<ul style="list-style-type: none"> Close the app. Power cycle the hearing aids by opening and closing the battery doors. Restart the app.
Overall volume level is too high or too low	<ul style="list-style-type: none"> You may go through the Concha Labs' mobile app to make adjustments (see "Adjust") or you may use the rocker switches on the hearing aids to raise and lower the volume.

11. Warranty

- The Concha Sol hearing aids are covered by a limited warranty. Visit our website at conchalabs.com/warranty for details of the limited warranty.
- This warranty excludes defects due to abuse or failure to use the product in accordance with instructions. This warranty is void in the event of unauthorised repair or modification, or removal or defacing of the product labelling.

Returns and Exchanges

- If you change your mind about the purchase of your Concha Labs product, or it is not performing as you think it should, you may have rights to return the product under:
 - The 2-year Concha Labs Manufacturer's Warranty.
 - The Concha Labs 60-Day Money Back Guarantee.
- If you experience any issues with the use, performance, or enjoyment of a Concha Labs' product, please contact us at +1 (510) 544-6778, or email us at care@conchalabs.com so we can assist you to resolve any issues as soon as possible.

12. Hearing Aid Technical Specifications

KEY FEATURES

Processing Channels	16
WDRC	Yes
Feedback Management	Yes

Battery	Disposable, Zinc Air, Size 312
Programs	Unlimited via app Program change via app or programmable earbud tap control
iOS App	Yes, compatible with iOS version 15 or later
Volume Control & Rocker Switch	Yes via app & Rocker Switch
Microphone Pattern	Directional
Self-Setup & Personalisation	Yes via app
Low Battery Alarm	Yes, user will hear a series of beeps
App Compatibility	iPhone 10 or later with iOS 15 or later
Hands-free Calling	Yes, wideband on supported devices

WIRELESS CONNECTIVITY

Bluetooth® Compatible	Yes, version 5.0
Bluetooth® Phone Call Compatible	Yes
Bluetooth® Music Stream Compatible	Yes

FITTING AND PROGRAMMING

Concha Labs App	Soundscope user-driven fitting and programming via app
Soundscope fitting frequencies	500 Hz to 8000 Hz
Soundscope fitting accounts for ear tips	Yes, open-fit silicon
Other components	1 pair of ear plugs

DIMENSIONS & ENVIRONMENTAL

Hearing Aid Dimensions	Diameter 17mm, depth 13mm
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TECHNICAL SPECIFICATIONS

Microphones	Two omnidirectional per hearing aid
Driver	Dynamic 9.2mm
Operating Range	Relative humidity between 10% and 90% Operating temperature between 32°F and 104°F (0 °C and 40 °C) Air pressure between 500 and 1100 hPa:

Transport and Storage

Temperature: -4°F to +140°F (-20°C to +60°C).
 Humidity: 10% to 60% RH NC.
 ATM Pressure: 500 to 1100 hP

Electroacoustic Characteristics (ANSI S3.22:2014 & CTA-2051:2017)	
Concha Sol OTC Hearing Aids	
Maximum Output Limit OSPL90	115.2 dB SPL
Full On Gain (FOG)	52.7 dB
Total Harmonic Distortion	Less than or equal to 1%
Self-Generated Noise Value	18.7 dB SPL
Latency Value	6.7 ms
Frequency Response Bandwidth	<200Hz - >10000 Hz
Frequency Response Smoothness	Maximum peak 1.7 dB
Input Distortion Clause	1.20%
Equivalent Input Noise (EIN)	18.6 dB SPL
Reference Test Gain (RTG)	36.3 dB

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The Concha Sol Hearing Aids are intended for use in the electromagnetic environment specified below. The customer or the user of the hearing aids should assure that it is used in such an environment.			
Emissions Test	IEC60601 test level	Compliance Level	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	Group 1	The hearing aids use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B	The hearing aids are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Complies	

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity	
The Concha Sol Hearing Aids are intended for use in the electromagnetic environment specified below. Hearing aid users and customers should ensure it is used in such an environment.	
Immunity Test	Compliance Level to IEC 60601
Electrostatic discharge (ESD) IEC 61000-4-2	<ul style="list-style-type: none"> ● <u>+ 8</u> kV contact ● <u>± 15</u> kV air
Radiated RF EM Fields IEC 61000-4-3	<ul style="list-style-type: none"> ● 10V/m ● 80 MHz – 2.7 GHz ● 80% AM at 1 kHz
Proximity fields from RF Wireless Communications equipment IEC 61000-4-3	<ul style="list-style-type: none"> ● 9V/m 710,745,780; MHz Pulse modulation 18 Hz ● 9V/m 5240,5500,5785 MHz; Pulse modulation 217 Hz ● 27V/m 385 MHz; Pulse modulation 18Hz ● 28V/m 450 MHz; FM +/- 5 kHz deviation; 1 kHz sine ● 28V/m 810, 870, 930 MHz ; Pulse modulation 18 Hz ● 28V/m 720,1845, 1970, 2450MHz; Pulse modulation 217 Hz

Features per ANSI/CTA 2051-2017

Feature Category	The Concha Sol Hearing Aids
Fixed or Level Dependent Frequency Equalization	Includes level dependent frequency equalization that is adjusted via user controls. Soundscape provides the ability to personalize, control and alter your soundscape. It is a process within the Concha Labs mobile app that allows you to create a hearing profile, shows your results, and calibrates your hearing aid for you.
Level Dependent Gain/Compression	The hearing aids feature a 16 band WDRC (Wide Dynamic Range Compression) System. WDRC makes soft speech sounds more audible, while louder sounds remain comfortable. This allows hearing aid users not to have to make as many manual adjustments to the volume of their hearing aids, as louder sounds will not be amplified beyond tolerance levels.
Feedback Control	The feedback control module relies on adaptive algorithms to cancel feedback and lower the overall gain if the feedback cannot be eliminated.
Personalization	Self-fitted by the user via the iOS app. The Soundscape tab in the Concha Labs mobile app allows you to measure and analyze your hearing thresholds. It then configures the hearing aids to reflect your own personal sound profile.
Coupling to the Ear	Uses open-fit silicone ear tips that have been ergonomically designed to fit most ears with a snug fit. The ear tips rest against the entrance of the ear canal.
Wireless Connectivity	Uses Bluetooth® technology for receiving streamed audio and for exchanging control data to a paired mobile device.

13. Clinical Data

Concha Sol Hearing Aids Clinical and Non-Clinical Data																							
<p>Concha Sol Hearing Aids Clinical Performance</p>	<p>Report: Clinical Performance Evaluation of the Concha Sol Hearing Aids</p> <p>The objective of the within-subject, randomized, crossover study design of the clinical investigation was to assess and evaluate the performance and clinical effectiveness of the Concha Sol self-fitting hearing aid, according to two distinct fitting methods. The first method involved users fitting the hearing aid devices themselves by relying exclusively on the provided smartphone application (Concha Labs App), without any intervention from a hearing care professional (SELF-FIT). The second method used the same hearing devices, but it was clinically fitted by a hearing care professional following industry best practices (CLIN-FIT).</p> <p><u>Study participant demographics</u></p> <p>Demographically, the study participants included a representative mix of female/male, age, and prior experience with hearing aids.</p> <p>Study Participant Demographic Information</p> <table border="1"> <thead> <tr> <th colspan="2">Demographic Factor</th> </tr> </thead> <tbody> <tr> <td colspan="2"><u>Sex</u></td> </tr> <tr> <td colspan="2">Number (%)</td> </tr> <tr> <td>Men</td> <td>13 (62.0)</td> </tr> <tr> <td>Women</td> <td>8 (38.0)</td> </tr> <tr> <td colspan="2"><u>Age, Years</u></td> </tr> <tr> <td>Mean (SD)</td> <td>66.2 (13.4)</td> </tr> <tr> <td>Median (IQR)</td> <td>73.0 (10.0)</td> </tr> <tr> <td colspan="2"><u>HA experience, (%)</u></td> </tr> <tr> <td>Inexperienced users</td> <td>17 (81.0)</td> </tr> <tr> <td>Experienced users</td> <td>4 (19.0)</td> </tr> </tbody> </table> <p>Additionally, while the ‘indications for use’ of the Concha Sol Hearing Aid stated the intended users have a <i>perceived mild to moderate hearing loss</i> - audiometric measures (air conduction audiogram for each ear per ANSI S3.6-2004) were taken at 500, 1,000, 2,000, 4,000 and 8,000 Hz. The results indicated that their measured hearing was consistent with that target population.</p> <p><u>Study endpoints and success criteria</u></p> <p><u>Effectiveness:</u></p>	Demographic Factor		<u>Sex</u>		Number (%)		Men	13 (62.0)	Women	8 (38.0)	<u>Age, Years</u>		Mean (SD)	66.2 (13.4)	Median (IQR)	73.0 (10.0)	<u>HA experience, (%)</u>		Inexperienced users	17 (81.0)	Experienced users	4 (19.0)
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	<p>A standardized measure of speech communication in noise, the Quick Speech-in-Noise (QuickSIN) Test was used as the primary effectiveness endpoint. A secondary effectiveness endpoint, the Abbreviated Profile of Hearing Aid Benefit (APHAB) was used to evaluate the effect on hearing impairment or benefit in daily life. Note that for each intervention, endpoints were measured at the end of the two-week take-home field trial.</p> <p>For the clinical study to be deemed successful, as with previous studies investigating the effectiveness of self-fitting relative to clinician-fitting (including the predicate device study; Sabin et al., 2020), a margin of 1.8 dB was defined for the QuickSIN benefit, and a margin of 9.9 selected for the APHAB benefit. For both assessed endpoints, the study results indicated comparable performance and satisfaction outcomes as revealed from clinical data as compared to the same hearing aid fit by a clinician.</p> <p>Safety: No device-related or other adverse events were observed over the course of the study. Also, no health-related issues due to device fit or discomfort were observed, and no device failures leading to potential safety issues were observed. These results suggest that the subject hearing aids are safe for its intended users.</p> <p>Conclusion: In conclusion, the clinical study demonstrated that the Concha Sol hearing aids are as safe and effective as the Bose predicate device (DEN180026). The Concha Sol hearing aids have the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device and raise no questions of safety and effectiveness when compared to the predicate.</p>
<p>Concha Sol Hearing Aids Performance: Human Factors/Usability</p>	<p>Report: Human factor/Usability testing of the Concha Sol Hearing Aids and Concha Labs app</p> <p>This study evaluated the essential and critical tasks associated with the intended users of the Concha Sol Hearing Aids and mobile app based on the device indications for use. Evidence supporting the safe and effective use of the hearing aid system was demonstrated in two studies:</p> <ul style="list-style-type: none"> ● Human factors/usability validation test in which 15 representative users attempted all critical tasks in the context of realistic use scenarios; ● Self-selection validation study in which 27 potential consumers determined if the hearing aid was appropriate for their needs based on pre-purchase information. <p>In addition to these validation studies, evidence for safe and effective use was supported through an extensive review and analysis of known use problems, a comprehensive analysis of use-related risk, and a series of three formative usability studies conducted prior to validation.</p>

14. Regulatory Compliance Information

FCC Part 15

NOTE: 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 Concha Labs 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 and Industry exposure limits set forth for the general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- Apple, iPhone, AirPlay, and App store are trademarks of Apple Inc., registered in the U.S. and other countries.
- The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth® SIG, Inc.




FCC ID: 00343-40661

























CL-1001



The Concha Sol Hearing Aids are a medical device meant for multiple uses by a single user.

Country	Type Approval	Regulatory Mark / Logo
Global	<p>The Concha Sol Hearing Aids comply with the following domestic and international regulations for medical devices: IEC 60601-1:2005 Ed3+C1, C2, A1, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-1-2 4th Edition, FCC 47 Part 15.247 Classification: Type B Applied Part, IEC 60601-2-66 The Concha Sol Hearing Aids have no essential performance. The testing performed above has been in accordance with IEC 60601-1-2:2014 (4th Ed). The values identified during this evaluation were found to be within acceptable specified ranges.</p>	

15. Symbols and Descriptions

Symbol	Description
	Review operating instructions prior to use
	Warning
	Model Number
	Serial Number
	Lot Number
	Magnetic field warning. Possible interference with cardiac pacemakers, implanted defibrillators (ICD's) and other implants
	Manufacturer
	Date of manufacture
	Contains small parts which may be a choking hazard. Not suitable for children under the age of 3
	Type B applied part
	WEEE Directive (Directive 2012/19/EU) and Battery Directive (Directive 2006/66/EC)
	Federal Communications Commission (U.S.)
	Bluetooth
	Apple AirPlay
	Product does not contain natural rubber latex
	Product is non-sterile
	Do NOT use if package is damaged
	Unique Device Identification (UDI)
	MR Unsafe
	Medical Device
	www.conchalabs.com
	Made in Germany
	Single patient, multiple use
	Keep dry

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MADE IN GERMANY