ADVANCED BIONICS
POWERFUL CONNECTIONS

A Sonova brand

AB Remote Support App

CI-6517

instructions for use
English

Contents

SYMBOLS TABLE	*4*
PURPOSE AND SCOPE OF IFU	*5*
INDICATIONS FOR USE	*5*
LIMITATIONS, CONTRAINDICATIONS	*7*
PRECAUTIONS, CAUTIONS, AND WARNINGS	*8*
UNDESIRABLE SIDE EFFECTS	*9*
PRODUCT DESCRIPTION AND PERFORMANCE CHARACTERISTICS	*9*

INTENDED PURPOSE ***10***
Intended Users *10*
Intended Patient Population *11*
Intended Use Environments *11*

COMPATIBILITY ***12***

CONNECTIVITY ***13***

PAIRING ***13***

INSTALLATION INSTRUCTIONS ***14***

USE INFORMATION ***18***

INSTRUCTIONS FOR USE ***45***

DISPOSAL ***59***

CLINICAL BENEFITS ***60***

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE ***61***

GUIDELINES FOR IT SECURITY ***62***

REMOTE PROGRAMMING CLINICAL STUDY RESULTS ***67***
Clinical Study Outcome *67*

Clinical Study Questionnaires ***69***
Participants Responses *69*
Investigators Responses *74*

SYMBOLS TABLE

Labeling symbols and their meanings:

CE 0123	European Community Mark of Conformity.
XXXX-XX-XX	Date of Manufacture
	Manufacturer
REF	Model number

	Caution (refer to “Cautions & Warnings” section for further information)
UDI	Unique Device Identifier
EC REP	European authorized representative
MD	Medical Device
	Consult Electronic Information for Use

PURPOSE AND SCOPE OF IFU

This IFU is designed to help cochlear implant recipients, and their caregivers if applicable, to appropriately use the AB Remote Support software. It is also meant to be used by hearing care professionals trained in the fitting of cochlear implants to counsel the recipients on the use of the AB Remote Support software.

INDICATIONS FOR USE

The AB Remote Support software is a component of the HiResolution™ Bionic Ear System, which is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss via electrical stimulation of the auditory nerve.

Adults

- *18 years of age or older.*
- *Severe-to-profound bilateral sensorineural hearing loss or severe-to-profound unilateral hearing loss.*
- *Post-lingual onset of severe or profound hearing loss.*
- *Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences).*

Children

- *12 months through 17 years of age.*
- *Severe-to-profound bilateral sensorineural deafness or severe-to-profound unilateral hearing loss. Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea.*
- *Little or no benefit from appropriately fitted hearing aids. In younger children (< 4 years of age), lack of benefit is defined as a failure to reach developmentally appropriate auditory milestones (such as spontaneous response to*

name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or ≤ 20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL). In older children (≥ 4 years of age), lack of hearing aid benefit is defined as scoring ≤12% on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or ≤ 30% on an open- set sentence test (Hearing In Noise Test for Children) administered using recorded materials in the sound field (70 dB SPL).

LIMITATIONS, CONTRAINDICATIONS

As the AB Remote Support software is a component of the HiResolution Bionic Ear System, the following contraindications stated for the HiResolution Bionic Ear System are applicable: Deafness due to lesions of the acoustic nerve or central auditory pathway; cochlear ossification that prevents electrode insertion; absence of cochlear development.

⚠ PRECAUTIONS, CAUTIONS, AND WARNINGS

- *Do not allow children to play with or operate the app unattended.*

- *Do not attempt to pair your sound processor or hearing aids to any accessories while driving or operating heavy machinery.*
- *Do not stream audio to your sound processor or hearing aids while driving or operating heavy machinery.*
- *Use your sound processor for hands-free phone use only where permitted by law and only when you will not be distracted from the safe operation of your motor vehicle.*
- *Instruct patient(s) capable of understanding your communication to remove the system headpiece if uncomfortable stimulation is encountered.*

- *Portable and mobile RF communications equipment, including radios and cellular phones, may affect sound quality of the Advanced Bionics Naída CI M and Sky CI M sound processors and accessories; however, there is no safety hazard associated with such equipment.*
- *Adjusting ambient balance while streaming audio (either with the multifunction button or with the mobile application) may interfere with the ability to be aware of surroundings.*
- *Do not attempt to service or modify the AB Remote App. Doing so may compromise system performance and will void the manufacturer's warranty. Products should be serviced only at Advanced Bionics and damaged products should be returned to Advanced Bionics.*

UNDESIRABLE SIDE EFFECTS

Undesirable side effects of using the app may include: Latency in stopping stimulation to halt an overly loud sound resulting in prolonged overly loud sound.

PRODUCT DESCRIPTION AND PERFORMANCE CHARACTERISTICS

The AB Remote Support app is designed to allow remote fitting support for Naída CI M/Sky Processor supported devices using Bluetooth connectivity. The app is designed to be the interface between the mobile device and Marvel supported devices to allow hearing care professionals to remotely program recipients in Target CI over WiFi/cellular connection.

INTENDED PURPOSE

The AB Remote Support app is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system.

The AB Remote Support application is designed to be used as the interface between Target CI fitting software and Advanced Bionics Naída CI M and Sky CI M sound processors as well as Phonak Naida Link M and Sky Link M hearing instruments. This application is installed on the cochlear implant recipient's mobile device and allows for remote support including troubleshooting, remote fitting, and diagnostic measurement.

Intended Users

The intended users of the AB Remote Support App are recipients, and their caregivers if applicable, of Advanced Bionics Naída CI M and Sky CI M sound processors, and hearing care professionals. It is not worn by the recipient and there is no minimum or maximum limit on the time that the software can be used.

The recipient, or their caregiver, should, at a minimum, be capable of changing the battery, connecting the earhook, placing and removing the sound processor from their ear, and placing and removing the headpiece from the implant site.

The hearing care professional should be trained in the use and fitting of the cochlear implant system.

Intended Patient Population

Adults – 18 years of age or older
Children – 12 months through 17 years of age

NOTE: Remote sessions are recommended for recipients who are 13+ years of age.

Intended Use Environments

The intended use environments of the AB Remote Support app are healthcare and daily living environments.

COMPATIBILITY

The AB Remote Support app is compatible with the following products:

- Advanced Bionics Naída CI M and Sky CI M sound processors with rechargeable batteries
- Phonak Naída Link M and Sky Link M hearing instruments
- Target CI version 1.5
- The minimum operating system (OS) requirements for the AB Remote Support app are:
  - Apple iOS 14 and above
  - Android 6 and above

The operating system compatibility information should be used as a reference guide only, because hardware and software levels and releases may vary, and numerous hardware and software combinations are possible.
AB assumes no responsibility for the compatibility thus it is the user's responsibility to do product compatibility testing by their self before any purchasing decision is taken.

Expected Lifetime

As a software product, the expected lifetime of this version of the AB Remote Support app is dependent on the availability of the above system requirements.

CONNECTIVITY

The Marvel CI Sound Processor has a Bluetooth connectivity range of 10 meters. Please ensure that your Bluetooth device stays within this range when using the app to maintain connection.

Connectivity errors resulting in loss of communication may require a hearing device reboot and a need to establish a new pairing connection.

PAIRING

NOTE: Hearing devices compatible with this app can remember only two pairings. If you have paired your hearing device with more than one other Bluetooth device since you last used the

AB Remote Support app, you will need to go to your phone Bluetooth settings, forget your hearing device, and follow the pairing instructions.

INSTALLATION INSTRUCTIONS

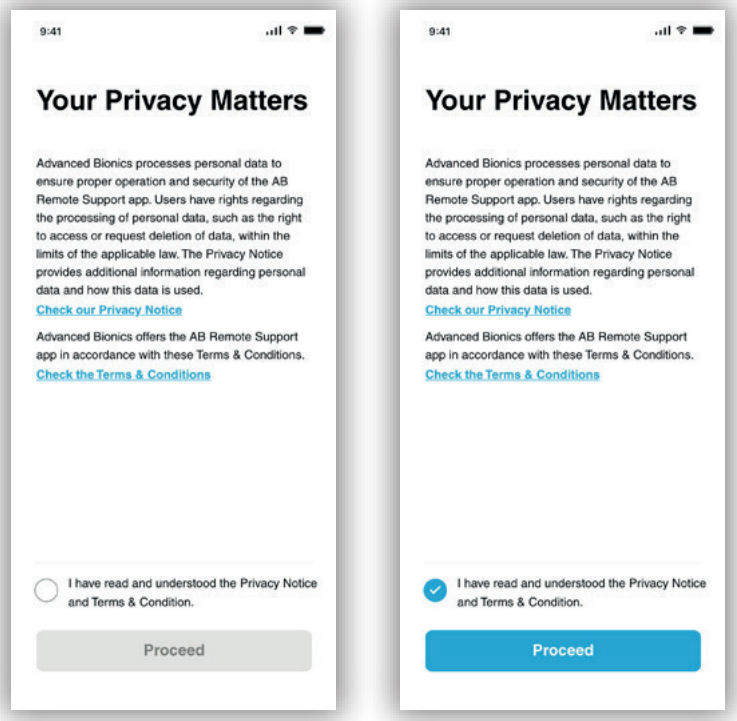
Installation

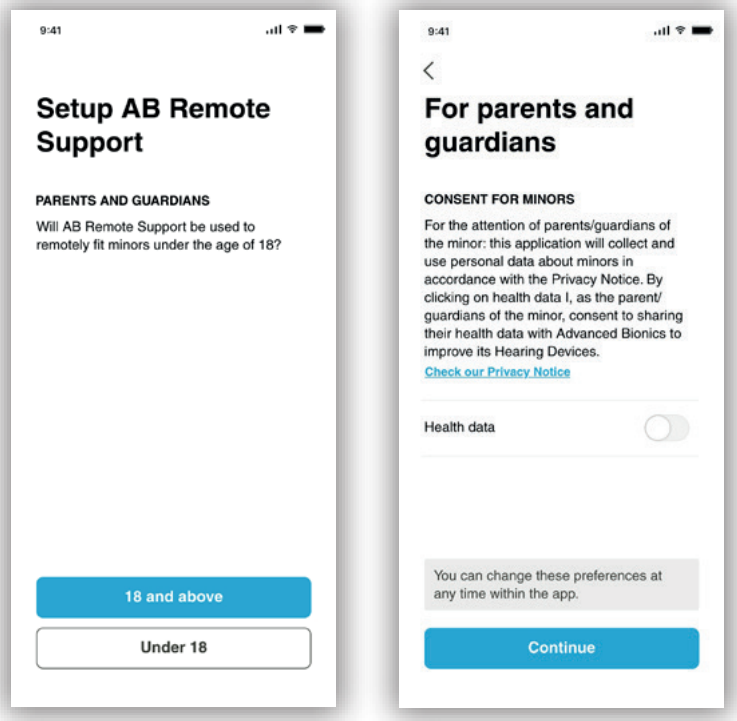
The AB Remote support app installs just like other apps that are installed on your phone.

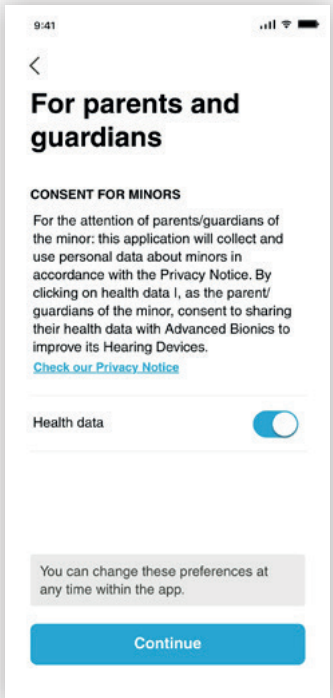
1. Connect your smartphone to the internet via WiFi or cellular data.
2. Turn on your smartphone's Bluetooth.
3. Download AB Remote support app from your devices online store. After installation open the app.

4. Age and consent – In order to use the app you must click “I agree to accept the age and consent requirements”.

5. Privacy Notice – In order to use the app you must click on “I have read and understood the Privacy Notice and Terms & Conditions”.


9:41
Your Privacy Matters
Advanced Bionics processes personal data to ensure proper operation and security of the AB Remote Support app. Users have rights regarding the processing of personal data, such as the right to access or request deletion of data, within the limits of the applicable law. The Privacy Notice provides additional information regarding personal data and how this data is used.
Check our Privacy Notice
Advanced Bionics offers the AB Remote Support app in accordance with these Terms & Conditions.
Check the Terms & Conditions
I have read and understood the Privacy Notice and Terms & Condition.
Proceed
9:41
Your Privacy Matters
Advanced Bionics processes personal data to ensure proper operation and security of the AB Remote Support app. Users have rights regarding the processing of personal data, such as the right to access or request deletion of data, within the limits of the applicable law. The Privacy Notice provides additional information regarding personal data and how this data is used.
Check our Privacy Notice
Advanced Bionics offers the AB Remote Support app in accordance with these Terms & Conditions.
Check the Terms & Conditions
I have read and understood the Privacy Notice and Terms & Condition.
Proceed


9:41
Setup AB Remote Support
PARENTS AND GUARDIANS
Will AB Remote Support be used to remotely fit minors under the age of 18?
18 and above
Under 18
9:41
For parents and guardians
CONSENT FOR MINORS
For the attention of parents/guardians of the minor: this application will collect and use personal data about minors in accordance with the Privacy Notice. By clicking on health data I, as the parent/ guardians of the minor, consent to sharing their health data with Advanced Bionics to improve its Hearing Devices.
Check our Privacy Notice
Health data
You can change these preferences at any time within the app.
Continue


9:41
For parents and guardians
CONSENT FOR MINORS
For the attention of parents/guardians of the minor: this application will collect and use personal data about minors in accordance with the Privacy Notice. By clicking on health data I, as the parent/ guardians of the minor, consent to sharing their health data with Advanced Bionics to improve its Hearing Devices.
Check our Privacy Notice
Health data
You can change these preferences at any time within the app.
Continue

USE INFORMATION

First use (and subsequent uses if Bluetooth memory is full)

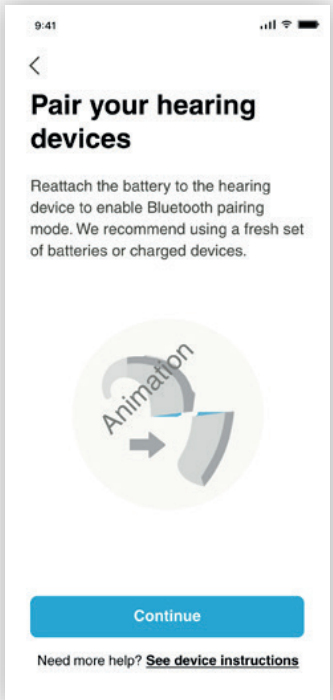
NOTE: We recommend using fully charged batteries. For non-rechargeable batteries, please refer to hearing aid instructions.

The very first time you install the app, you will be guided to pair your devices in 3 simple steps:

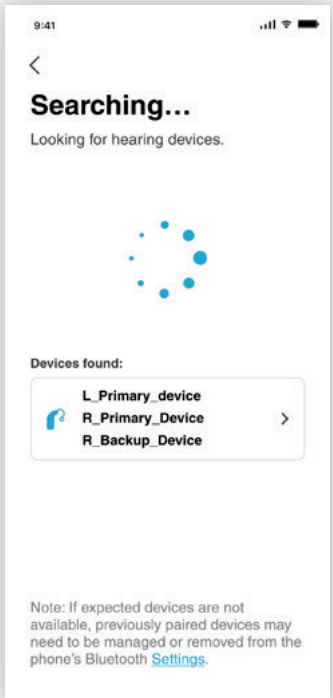
1. Turn your devices off and then on to put them into pairing mode by removing the battery from the processor and sliding the battery back on. The app will also have additional instructions to assist.

NOTE: When pairing more than one hearing device, you may need to restart the hearing devices together to view all devices in pairing.

NOTE: Only sound processors and hearing aids are paired to AB Remote Support app. For sound processors using a CROS device, please pair the sound processor only.

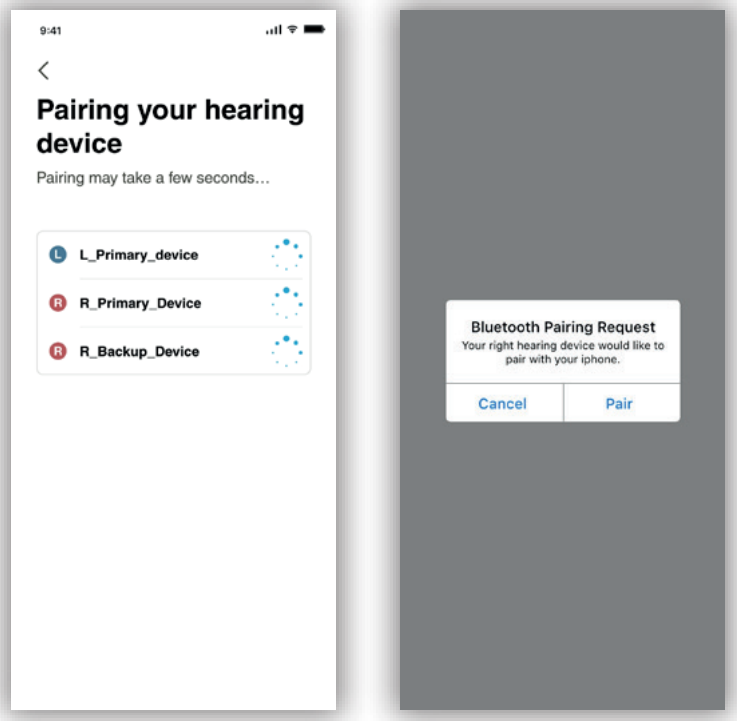

9:41
Pair your hearing devices
Reattach the battery to the hearing device to enable Bluetooth pairing mode. We recommend using a fresh set of batteries or charged devices.
Animation
Continue
Need more help? See device instructions

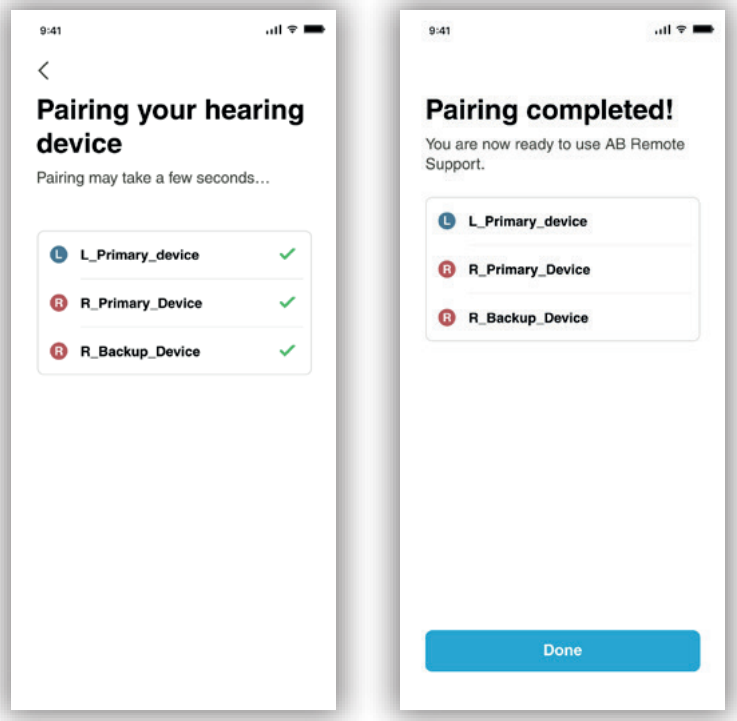
2. View your devices in the list of available devices.



NOTE: If expected devices are not available, previously paired devices may need to be managed or removed from the phone's Bluetooth Settings.

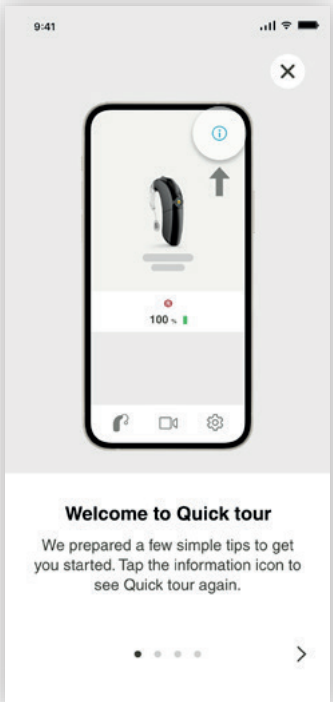
3. Tap the card to pair your devices.




9:41
Pairing your hearing device
Pairing may take a few seconds…
L_Primary_device
R_Primary_Device
R_Backup_Device
9:41
Pairing completed!
You are now ready to use AB Remote Support.
L_Primary_device
R_Primary_Device
R_Backup_Device
Done

NOTE: If you have a hearing device on the left and right side, they are paired and connected together in one step.

Quick Tour


9:41
100
Welcome to Quick tour
We prepared a few simple tips to get you started. Tap the information icon to see Quick tour again.

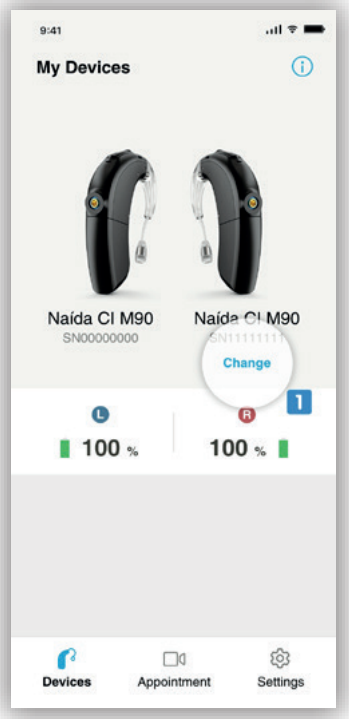
The Quick Tour will be displayed the first time you run the app. At any time, you can access tips again via the “Settings” > “Quick Tour” [See also “Settings” Menu details].

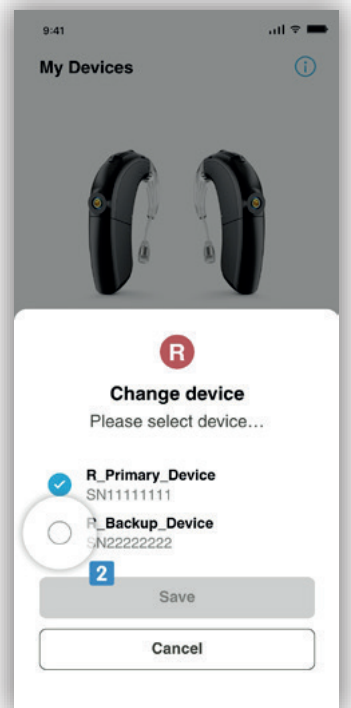
Changing or Removing Paired Devices

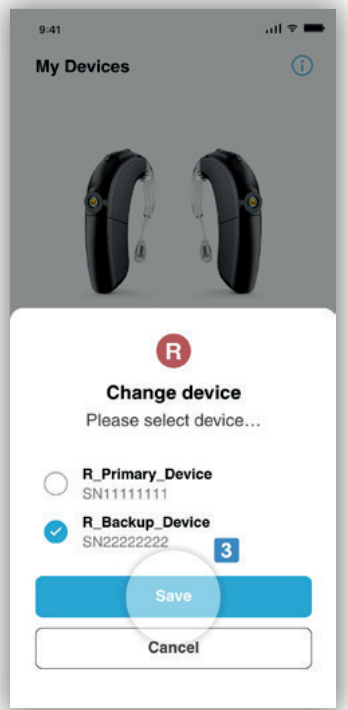
You may have a need to change or remove the devices that are paired. For example, if you switch phones, or if you have replacement hearing devices.

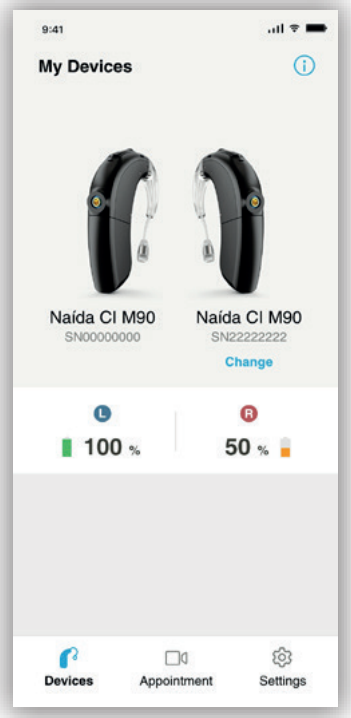
NOTE: You will need to remove this device from the phone’s Bluetooth settings and pair again to use with AB Remote Support app.

Change between primary and backup devices method 1:

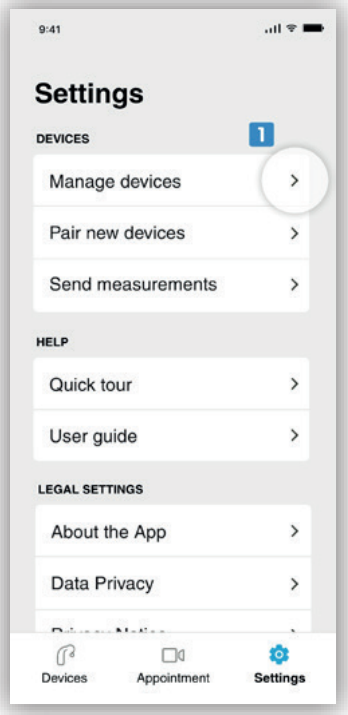


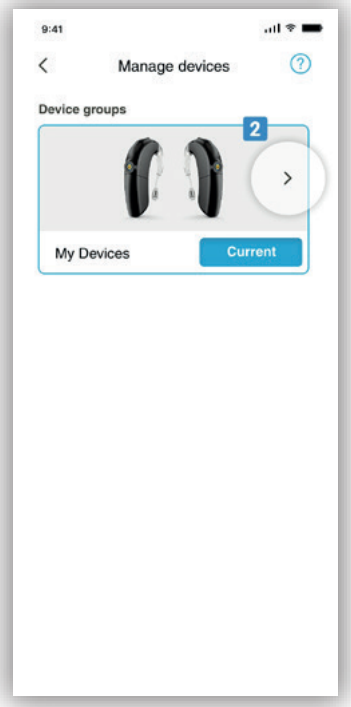


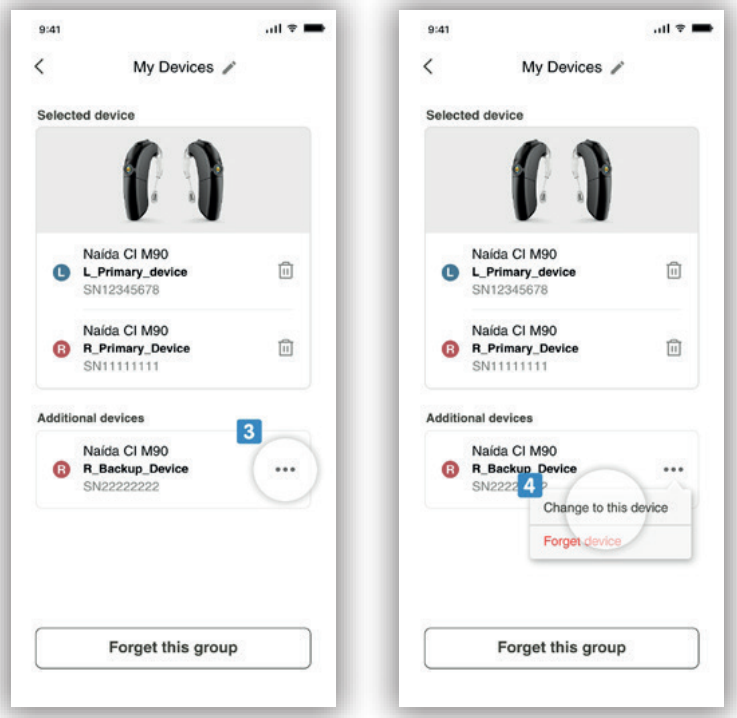

9:41
My Devices
R
Change device
Please select device...
R_Primary_Device
SN11111111
R_Backup_Device
SN22222222
3
Save
Cancel

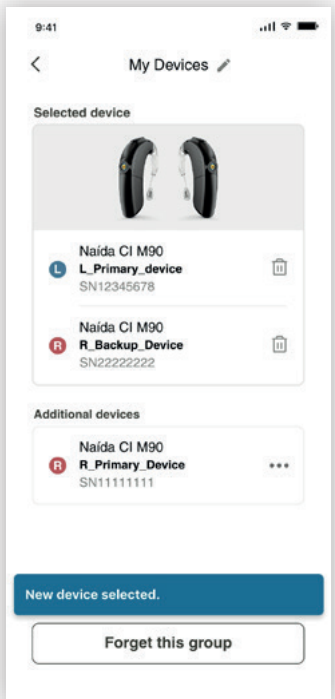

9:41
My Devices
Naída CI M90
SN00000000
Naída CI M90
SN22222222
Change
L
100 %
R
50 %
Devices
Appointment
Settings

Change between primary and backup devices method 2:



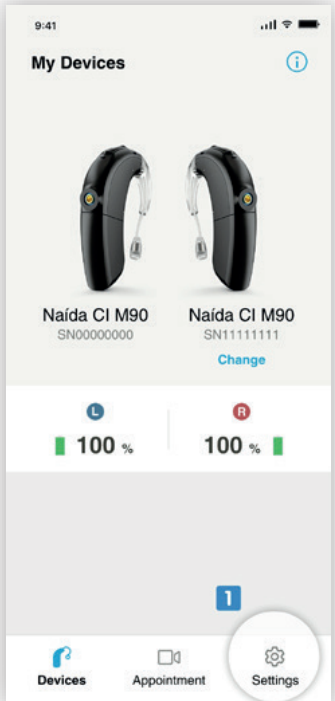



9:41
My Devices
Selected device
Naída CI M90
L_Primary_device
SN12345678
Naída CI M90
R_Primary_Device
SN11111111
Additional devices
Naída CI M90
R_Backup_Device
SN22222222
3
Forget this group
9:41
My Devices
Selected device
Naída CI M90
L_Primary_device
SN12345678
Naída CI M90
R_Primary_Device
SN11111111
Additional devices
Naída CI M90
R_Backup_Device
4
Change to this device
Forget device
Forget this group

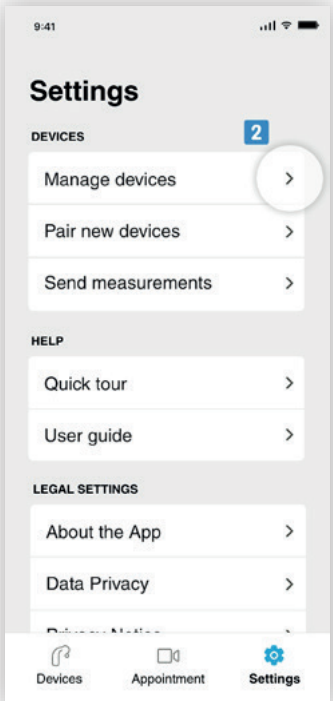

9:41
My Devices
Selected device
Naída CI M90
L_Primary_device
SN12345678
Naída CI M90
R_Backup_Device
SN22222222
Additional devices
Naída CI M90
R_Primary_Device
SN11111111
New device selected.
Forget this group

Removing paired devices

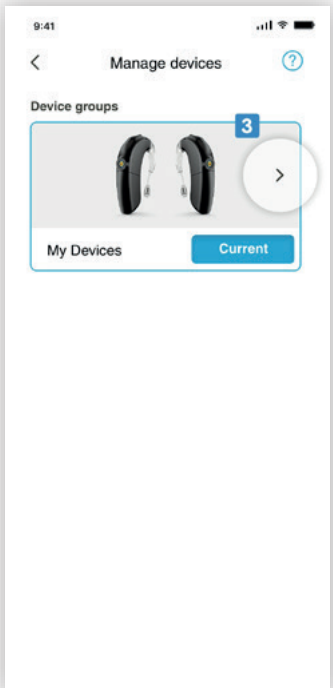
1. Tap the “Settings” icon in the navigation bar on the bottom right corner for settings and help.


9:41
My Devices
Naída CI M90
SN00000000
Naída CI M90
SN11111111
Change
L
100 %
R
100 %
1
Devices
Appointment
Settings

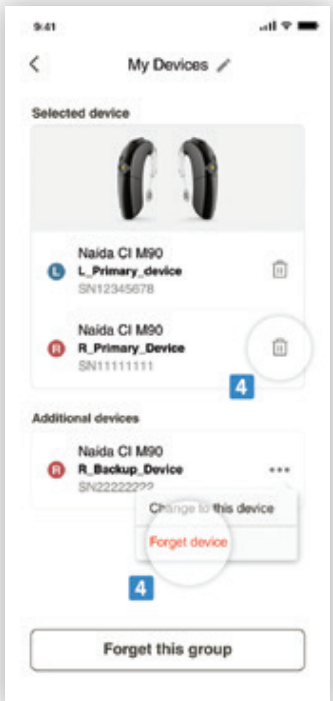
2. Tap “Manage devices”.



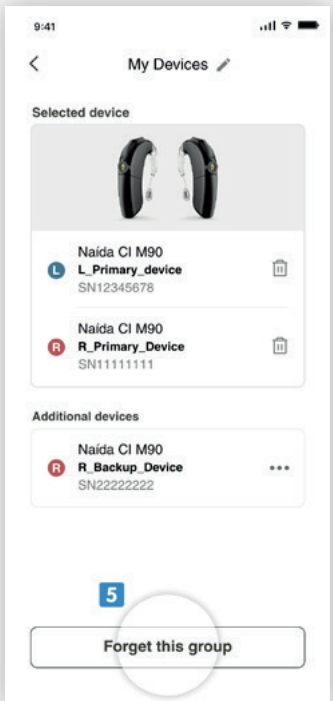
3. Tap “My Devices” card.



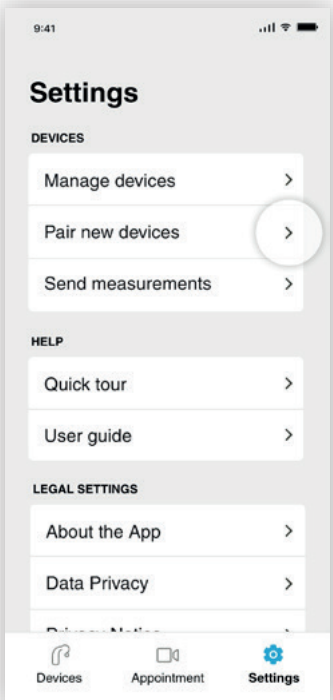
4. Tap trash can icon or three dotted menu button and tap “Forget device” to remove single device.



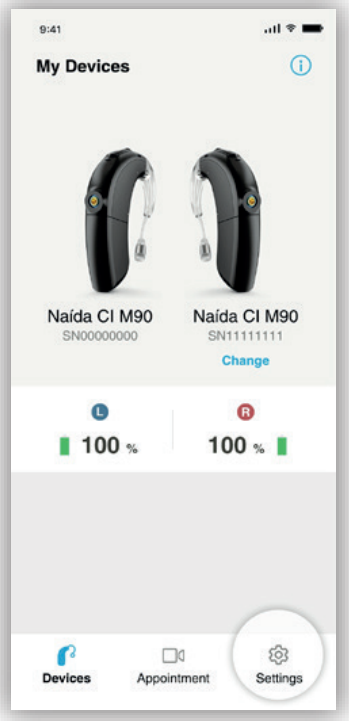
5. Tap “Forget this group” button shown to remove all the devices in this group.

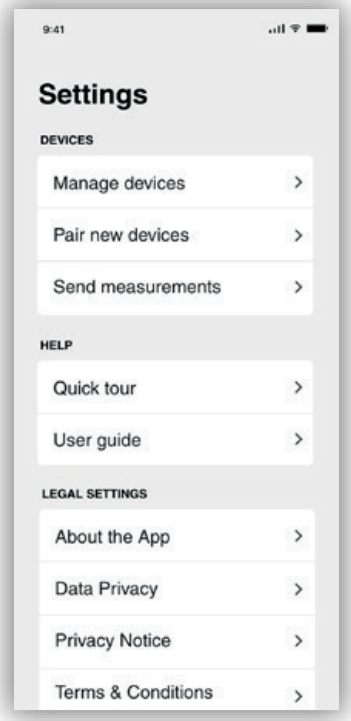


6. You may now pair new devices as described above.



Settings

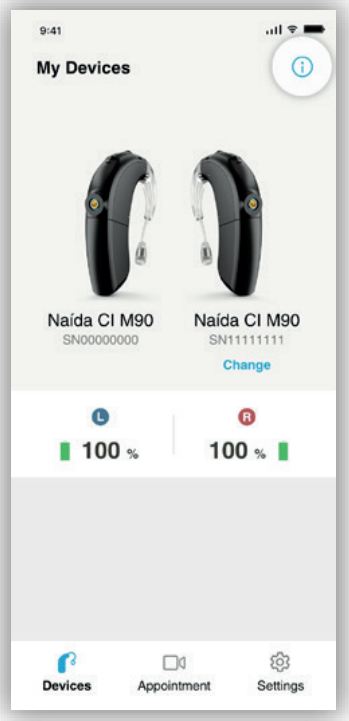

9:41
My Devices
Naída CI M90
SN00000000
Naída CI M90
SN11111111
Change
L
100 %
R
100 %
Devices
Appointment
Settings

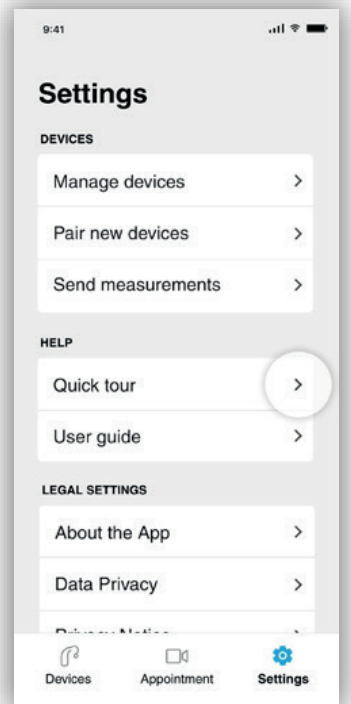

9:41
Settings
DEVICES
Manage devices
Pair new devices
Send measurements
HELP
Quick tour
User guide
LEGAL SETTINGS
About the App
Data Privacy
Privacy Notice
Terms & Conditions

Quick Tour

The AB Remote app includes helpful Quick Tour.

Quick Tour will be displayed the first time you run the app. At any time, you can access tips again by clicking this  icon in the top left corner of the app:

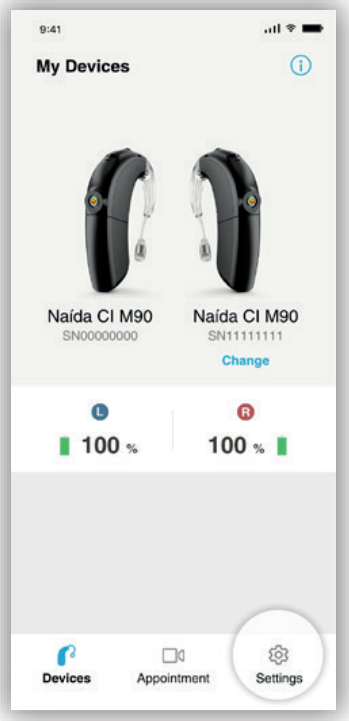

9:41
My Devices
Naída CI M90
SN00000000
Naída CI M90
SN11111111
Change
100 %
100 %
Devices
Appointment
Settings

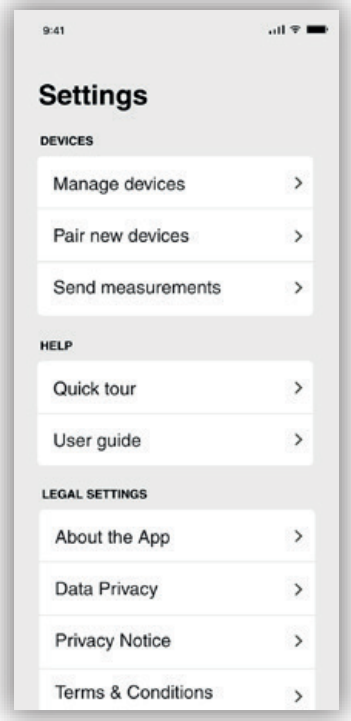

9:41
Settings
DEVICES
Manage devices
Pair new devices
Send measurements
HELP
Quick tour
User guide
LEGAL SETTINGS
About the App
Data Privacy
Devices
Appointment
Settings

Most of the common tasks you will need to do are explained in the tips section.

Devices, Help, and Legal Settings

Additional device help, and legal settings can be found by clicking the “Settings” icon in the bottom right corner of the app.


9:41
My Devices
Naída CI M90
SN00000000
Naída CI M90
SN11111111
Change
L
100 %
R
100 %
Devices
Appointment
Settings


9:41
Settings
DEVICES
Manage devices
Pair new devices
Send measurements
HELP
Quick tour
User guide
LEGAL SETTINGS
About the App
Data Privacy
Privacy Notice
Terms & Conditions

From there, the following menu items are available:

“Manage Devices”

“Pair New Devices”

“Send Measurements”

“Quick Tour”

“User Guide”

“About the App”

“Privacy Notice”

“Terms & Conditions”

“Health Preferences”

“Data Privacy”

INSTRUCTIONS FOR USE

Prepare for your virtual appointment

A virtual appointment allows your hearing care professional to test hearing device settings and make real-time adjustment in any environment. This will require internet access prior to the virtual appointment.

To schedule your virtual appointment, please contact your hearing care professional.

NOTE: Cellular Data Usage: **If using cellular data, your mobile provider may charge you. Please check with your phone provider before starting a AB Remote Support session.**

A Remote Support session will use around 56 MB for a 10 minute video call, while an audio call uses around 30 MB.

NOTE: Remote sessions are recommended for recipients who are 13+ years of age.

NOTE: An initial programming session must be performed with your programming professional in order to enable a Remote Support virtual appointment.

Once your virtual appointment is scheduled, please follow the steps below to prepare:

- Use new or fully charged batteries for all hearing devices being programmed during your virtual appointment.

- Test your internet connection, inadequate internet speeds can result in video and audio delays. WiFi is recommended to avoid potential data charges.
- Enable access to your mobile device camera and microphone in the mobile device Settings. Camera and microphone can be manually disabled during the virtual appointment.
- Use your mobile device power cord to charge your mobile device.
- Confirm hearing devices are paired to the AB Remote Support app. If applicable, backup devices can be paired in app Settings.

Before your appointment

- Confirm hearing devices are on and connected to the AB Remote Support app. If applicable, turn on backup devices and confirm they are available for selection.
- If using devices on both ears, please ensure both devices are on and within range of each other. When using backup devices, ensure they are OFF and fully charged until your audiologist asks you to connect them.
- Press “Join waiting room” at the time of your appointment. Your hearing care professional will join when ready for your visit.

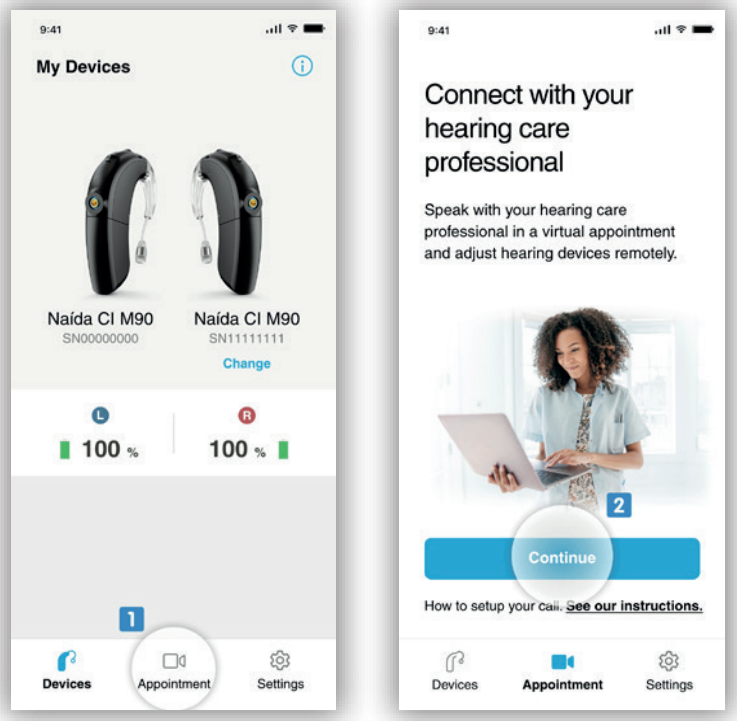
During the appointment

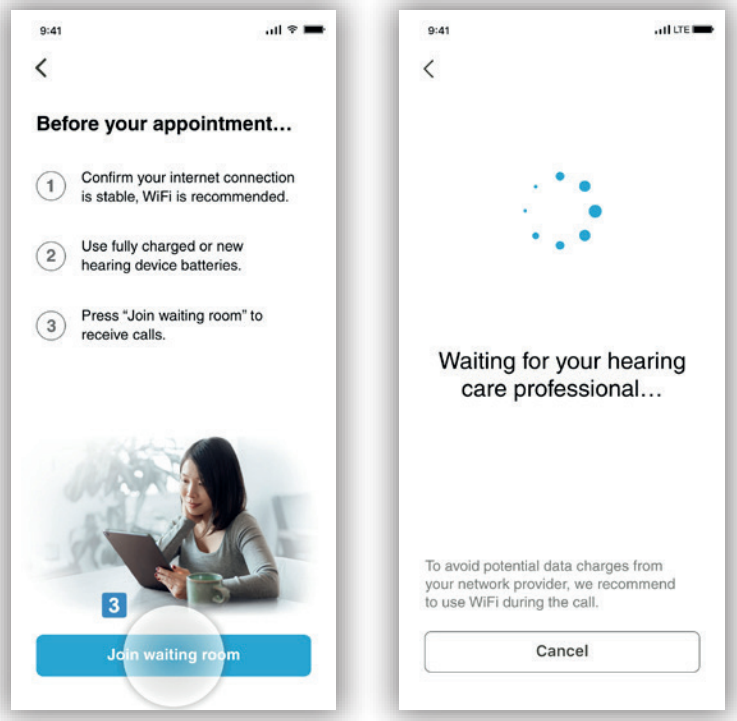
- Please remain in the AB Remote Support app. It is not recommended to take phone calls or navigate away from the app once the fitting has started.

Navigating away from the app (either by opening a second app or accepting a phone call) during a remote fitting session could result in a connection disturbance causing the device(s) to mute.

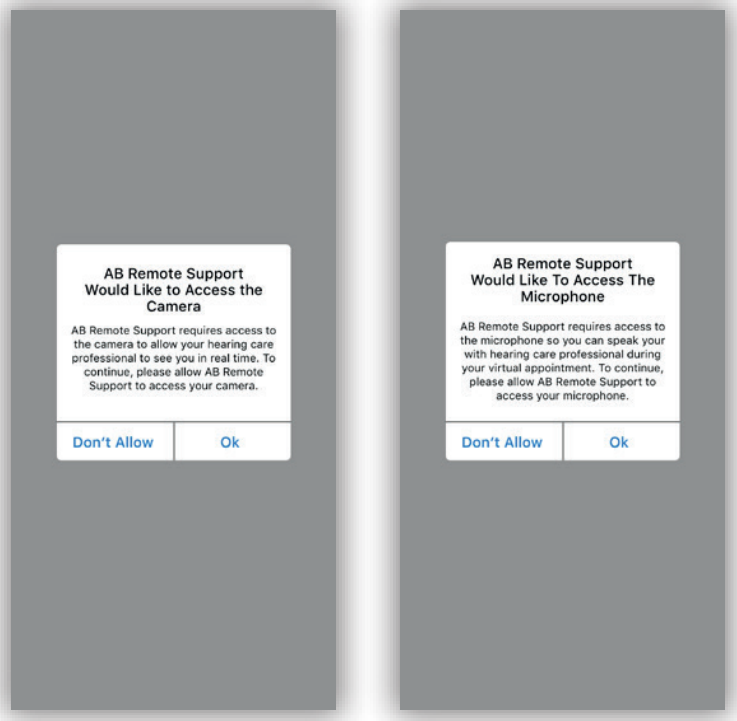
Start the Remote Support session

Immediately before your appointment, open the AB Remote Support app and tap on “Continue” to let your hearing care professional know that you are ready for your AB Remote Support appointment.


9:41
My Devices
Naída CI M90
SN00000000
Naída CI M90
SN11111111
Change
100 %
100 %
1
Devices
Appointment
Settings
9:41
Connect with your hearing care professional
Speak with your hearing care professional in a virtual appointment and adjust hearing devices remotely.
2
Continue
How to setup your call. See our instructions.
Devices
Appointment
Settings

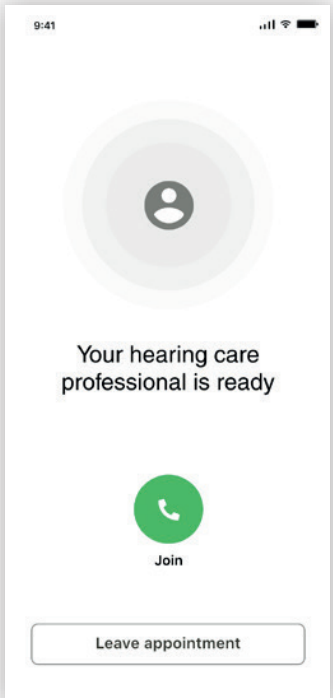

9:41
Before your appointment...
1 Confirm your internet connection is stable, WiFi is recommended.
2 Use fully charged or new hearing device batteries.
3 Press "Join waiting room" to receive calls.
3
Join waiting room
9:41
LTE
Waiting for your hearing care professional...
To avoid potential data charges from your network provider, we recommend to use WiFi during the call.
Cancel

Access to camera and microphone – Tap on “OK” to allow the AB Remote Support app to access your camera and microphone.


AB Remote Support
Would Like to Access the
Camera
AB Remote Support requires access to the camera to allow your hearing care professional to see you in real time. To continue, please allow AB Remote Support to access your camera.
Don't Allow
Ok
AB Remote Support
Would Like To Access The
Microphone
AB Remote Support requires access to the microphone so you can speak your with hearing care professional during your virtual appointment. To continue, please allow AB Remote Support to access your microphone.
Don't Allow
Ok

NOTE: If you have an Android smartphone tap on “ALLOW” to give AB Remote Support app permission to make and manage calls

Accept video calls – The app will connect you to a hearing care professional. Tap on “Join” to join the call from your hearing care professional.


9:41
Your hearing care professional is ready
Join
Leave appointment

Remote Support Session (cont.)



While in the Remote Support session you can personalize your experience by turning on or off your Video or Audio.

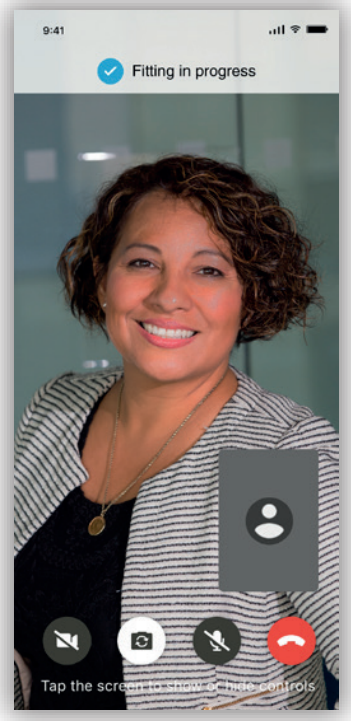
Starting a video call – After a few seconds the video image is set up and you can see your hearing care professional.

Ongoing call – You are now connected to your hearing care professional.


9:41
Fitting in progress

Connected cochlear implants – If your hearing care professional needs to connect to your cochlear implants, this can be done remote using your smartphone. Your hearing care professional will let you know when he or she connects to your cochlear implants.


9:41
Fitting starting
Tap the screen to show/hide controls


9:41
Fitting in progress
Tap the screen to show/hide controls

No video – If you wish to hide your video, you can disable the video with the click of a button.

New settings saved – Your cochlear implants will mute briefly during the connection process and while settings are being saved to your cochlear implants. You will be able to see the status on your screen.

NOTE: In the event that the connection between the recipient's hearing devices and fitting software gets interrupted during an active Remote Support session, the hearing instruments will mute. If the connection is lost the professional will need to re-establish connection to the instrument(s) in order to resume programming.

DISPOSAL

The AB Remote Support app can be removed at any time from the users Smart Phone using existing standard operating system features to remove any app. The AB Remote Support app does not collect or store user data on the app. No special provisions are required to remove user data.

CLINICAL BENEFITS

Target CI has no direct clinical benefit when used without connection to a Naída CI M/Sky sound processor.

The intended clinical benefit of Target CI as part of the HiResolution Bionic Ear System is:

For adults:

- *Word recognition score in quiet higher or equal to 30% at a minimum of 12 months follow-up OR improvement higher than 30% compared to pre-operative stage*

AND/OR

- *Sentence recognition score in quiet higher or equal to 40% at a minimum of 12 months follow-up OR improvement higher than 40% compared to pre-operative stage*

For children:

- *Before 4 years old: auditory awareness higher than 50% at a minimum of 12 months follow-up*
- *Above 4 years old: word/sentence recognition in quiet higher than 30% or improvement of 30% at a minimum of 12 months follow-up.*

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

A summary of safety and clinical performance (SSCP) is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI: 08400944CI6517YL https://ec.europa.eu/tools/eudamed

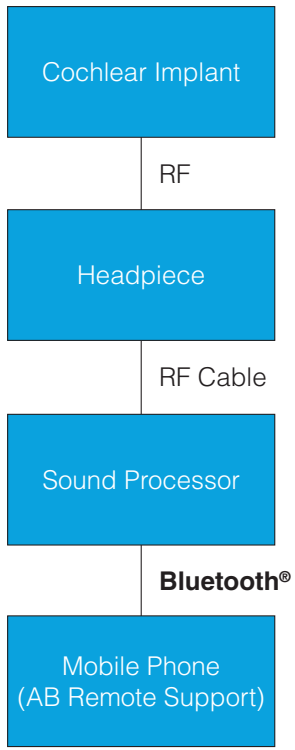
Users of the AB Remote Support app in the European Union should report any serious incident to their local competent authority and to Advanced Bionics.

GUIDELINES FOR IT SECURITY

Intended Use Environment

The AB Remote Support app is intended for use in healthcare and home environments. The home environment is extended to include use outdoors and during travel (e.g., airplanes). The AB Remote Support application is intended to operate with Advanced Bionics Naída CI M and Sky CI M sound processors and Phonak Naída Link M and Sky Link M hearing instruments. The user is responsible for security of connections with other devices, including pairing the sound processor with other devices in a secure environment.

System and Network Diagram



System Interfaces & Connectivity

Component	Interface	Communication Protocol
Advanced Bionics Naída CI M sound processors **Advanced Bionics Sky CI M sound processors** **Phonak Naída Link M hearing instruments** **Phonak Sky Link M hearing instruments**	Bluetooth 4.2	Bluetooth 4.2

Cybersecurity Configuration

There is no specific AB Remote Support configuration needed to help ensure cybersecurity. Ensure pairing with Bluetooth devices is completed in a secure environment.

Integrated Cybersecurity Functions

Advanced Bionics Naída CI M and Sky CI M sound processors and AB Remote app do not include user authorization or authentication mechanisms. Each sound processor is uniquely configured to connect with a single Advanced Bionics cochlear implant as fitted by the Hearing Health Professional. Data integrity and quality of service is ensured through sound processor and implant error correction and detection mechanisms.

System, Configuration, and Data Backup/Restore

The AB Remote Support App does not provide System, Configuration or Data Backup/Restore functions. The user should visit his or her cochlear implant professional for any changes or restorations of sound processor settings.

Cybersecurity Incident Response

The AB Remote Support App does not detect cybersecurity attacks or intrusions. In case of abnormal behavior of the AB Remote app or sound processor, please contact Advanced Bionics.

Patches and Updates

Advanced Bionics may release software updates from time to time to address defects or enhance features.
The software updates will be notified through the existing app store mechanisms.

Available Training

Visit https://www.advancedbionics.com/ or contact your Advanced Bionics representative to find further information and training tools.

End of Cybersecurity Support

Advanced Bionics Apps and Sound Processors are supported until they no longer have regulatory approval in the country of use or until the product is obsolesced by Advanced Bionics.

REMOTE PROGRAMMING CLINICAL STUDY RESULTS

Clinical Study Outcome

Advanced Bionics completed a multicenter clinical study of remote sound processor programming using the Naída CI M90 sound processor and investigational version of the Target CI version 1.5 programming software and AB Remote Support application. Results from the clinical study are summarized.

Seventeen participants with ages ranging between 15 and 84 years completed the clinical study. The listening modality for twelve of these participants was electric stimulation only, the remaining five wore the Advanced Bionics acoustic earhook for combined electric and acoustic stimulation.

The table below summarizes the comparison of speech understanding in quiet following an in-office clinical fitting and a remote clinical fitting. Speech understanding was similar between the two types of cochlear implant fitting.

	Average AzBio Sentence Score (%) In-Office Fitting	Average AzBio Sentence Score (%) Remote Fitting
N	17	17
Mean (SD)	89.04 (10.964)	90.99 (8.613)
Median	93.90	93.80

The similarity in speech understanding following in-office and remote cochlear implant fittings shows that remote cochlear implant fitting did not result in inferior speech understanding.

Clinical Study Questionnaires

Participants Responses

Participants in this study completed questionnaires that asked about their subjective experience during remote programming. The tables below show the total number of responses to each of 10 questions. Overall, responses to the remote fitting questionnaire were in agreement. The remote fitting experience was accepted by subjects and comparable to an in-clinic visit. Technical limitations associated with a wireless internet connectivity were expected, as they are part of any internet connected system.

1. Communication between the parties was acceptable during this session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	0	0	3	14

2. The technology was easy to use during this fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	2	0	4	10

3. I was able to complete this fitting session without additional technical assistance				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	3	0	2	11

4. This type of fitting is acceptable				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	0	5	2	10

5. All my needs could be addressed during this fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	0	1	4	12

6. I received the same level of care during this fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	1	0	1	15

7. My interaction with the audiologist is similar during this type of fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	1	1	4	11

8. I would want to use this type of fitting in the future on a regular basis				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	2	4	2	9

9. I would only want to use this type of fitting in the future if other options are impractical				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	0	5	3	8

10. I would recommend this type of fitting to friends or family who use cochlear implants					
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree	N/A
0	0	2	4	10	1

Investigators Responses

Investigators in this study completed questionnaires that asked about their subjective experience during remote programming. The tables below show the total number of responses to each of 10 questions. Overall, responses to the investigator's remote fitting questionnaire were in agreement. The remote fitting

experience was accepted by the investigators and judged as easy to use. Technical limitations associated with a wireless internet connectivity were expected and resolved, largely without technical assistance. As expected, some of the investigator responses indicate that remote programming will not be a solution for all patients or all visits, but it would be recommended as an alternative to some in-clinic visits.

1. Communication between the parties was acceptable during this session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	2	0	6	8

2. The technology was easy to use during this fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	1	0	7	8

3. I was able to complete this fitting session without additional technical assistance				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	1	0	6	9

4. I was able to overcome any technical issues encountered during the session (e.g. signal delays, internet speeds, connection problems).				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	0	1	9	7

5. This type of fitting is acceptable				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	2	2	3	9

6. All my subject's needs could be addressed during this fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	2	3	4	7

7. I was able to provide the same level of care during this fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	5	0	8	3

8. My interaction with the subject is similar during this type of fitting session				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	7	1	7	1

9. I would want to use this type of fitting in the future on a regular basis				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	3	4	4	6

10. I would only want to use this type of fitting in the future if other options are impractical				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
1	4	2	6	4

11. I would recommend this type of fitting to my patients who use cochlear implants				
1 - Strongly Disagree	2 - Slightly Disagree	3 - Neither Agree nor Disagree	4 - Slightly Agree	5 - Strongly Agree
0	4	1	5	7

Advanced Bionics LLC
28515 Westinghouse Place
Valencia, CA 91355, USA
Tel: +1 661-362-1400

EC REP Advanced Bionics GmbH
Feodor-Lynen-Strasse 35
D-30625 Hannover
Tel: +49 511 5248 7522

CE 0123

AB – A Sonova brand

AdvancedBionics.com

029-Q872-02

029-Q872-02 Rev A 2023-09-22
©2023 Advanced Bionics LLC. All Rights Reserved.