



ReSound GN

ReSound Smart Fit™

User guide

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Introduction

Intended Purpose

Fitting Software is computer software that is intended to program a hearing aid according to the needs of the specific user.

Target Group

The fitting software is intended to be used by qualified hearing care professionals.

Symbols



WARNING points out a situation that could lead to serious injuries.

CAUTION indicates a situation that could lead to minor and moderate injuries.



Advice and tips on how to handle your fitting software better.

How to start

This fitting software, Resound Smart Fit, must be installed and used by hearing care professionals only. It is recommended to always update the fitting software to the latest version available.

For additional support materials please visit

<https://pro.resound.com/en-us/products/support-materials>


System requirements

Before installing ReSound Smart Fit, it is necessary to make sure that you are all set with your computer and programming interfaces. The requirements are summarized in the table below. Please note that fitting software does not support running on mobile devices or tablets.

For wired programming, an adapter cable/connector system or adapter flex strip is needed to connect to the hearing aids. Those cable systems can be purchased either through the current supplier or through other suppliers in the market.


The descriptions for the different connector systems are listed in the table below. For overview of the cable systems and products, please see the Cable and Wireless Fitting Guide.

Adapter cable to connect mini-DIN to a small round plug (3 mm diameter) with 4 connections
Adapter cable to connect mini-DIN to a small round plug (3 mm diameter) with 5 connections
Adapter flex strip to connect a small 4 pin socket (3mm diameter) to a 3-pin contact pad
Adapter flex strip to connect a small 4 pin socket (3 mm diameter) to a 4-pin contact pad
Adapter cable to connect mini-DIN to a flex with 3-contact pads via a clip module
Adapter cable to connect mini-DIN to a flex with 4 contact pads via a clip module

SUPPORTED OPERATING SYSTEMS	
	Windows 7 – 32 & 64-bit – All service packs
	<ul style="list-style-type: none"> Windows 8.1 – 32 & 64-bit – All service packs Windows 10 – 32 & 64-bit – All service packs
<i>Windows XP, Windows Vista and Windows 8 are not supported.</i>	
SUPPORTED PATIENT DATABASE	
	<ul style="list-style-type: none"> Noah 4
<i>Noah 2 and Noah 3 are not supported.</i>	
SUPPORTED PROGRAMMING INTERFACES	
	<ul style="list-style-type: none"> NOAHlink Wireless Speedlink NOAHlink Hi-PRO/Hi-PRO2 (USB)
<i>Airlink dongle is not supported.</i>	
Note - If you have Airlink 2, you need to update its firmware to be able to connect the new ReSound products. Please follow the instructions on ReSound Smart Fit.	

SUPPORTED REM MODULES	
MANUFACTURER	MODULE NAME
Otometrics	OTOSuite
Interacoustics	Callisto Suite
MedRx	Avant REM
Sivantos	Unity 3
Auditdata	Primus
Interacoustics	Affinity Suite

* Manufacturer and module compatibility is subject to change. Please contact customer support for the latest information.

PC REQUIREMENTS	MINIMUM PC REQUIREMENTS	RECOMMENDED PC REQUIREMENTS
Processor	Intel Core i3 processor or similar	* Intel Core i7 processor or similar
RAM	4 GB	* 8 GB
Free Hard Disk Space	8 GB	10 GB
Screen Resolution	Full Screen - 1280 x 1024 Wide Screen - 1366 X 768	* Full Screen - 1400 x 1050 * Wide Screen - 1920 x 1080
Operating systems	 Windows 7 - 32bit/*64bit (SP1 or higher)	Windows 10 - 64-bit
Noah	4.12.1	4.12.1 (or higher)
Internet Browsers	<ul style="list-style-type: none"> Internet Explorer (IE) – version 11 (or higher) Google Chrome – version 41 and 42 (or higher) Firefox – version 39 and 40 (or higher) Safari – version 7 (or higher) <i>Mobile browser is not supported.</i>	
Ports	USB 2.0 Port (or higher)	
Drives	DVD-ROM	
Sound Card	16 bit, stereo, Microsoft DirectSound and DirectSound 3D compatible	
External Equipment	Printer, *Camera and *Microphone	

* These specifications are required for the Live Assistance feature in fitting software.

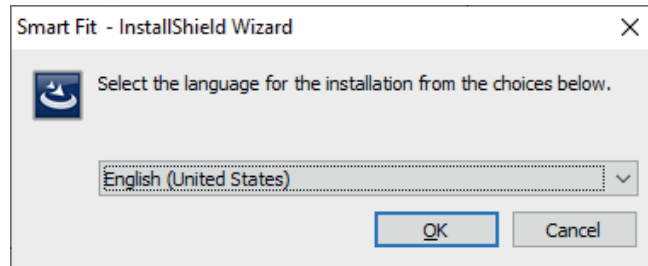
 It is required to have Extended Security Updates for Windows 7. Please visit Microsoft website for more information.

Please make sure to meet the minimum system requirements to avoid errors while installing, or slow performance. Performance can be optimized by adherence to recommended PC requirements.

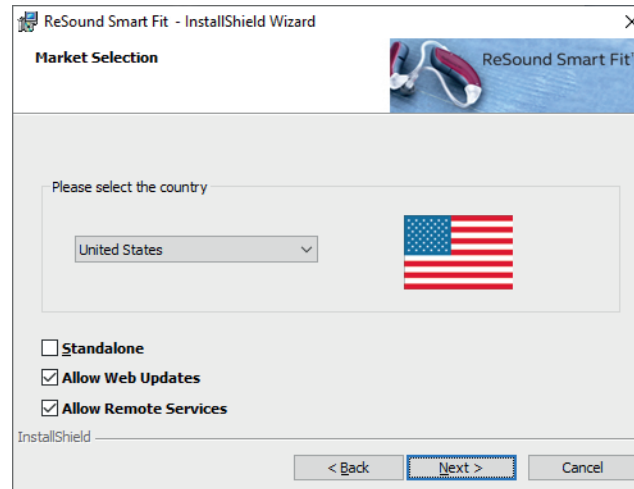


WARNING: Installation of fitting software on a PC that does not meet minimum system requirements may result in unexpected closing of the fitting software. Unexpected closing of the fitting software while hearing aids are connected may result in unpredictable behavior, including loud sounds that may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

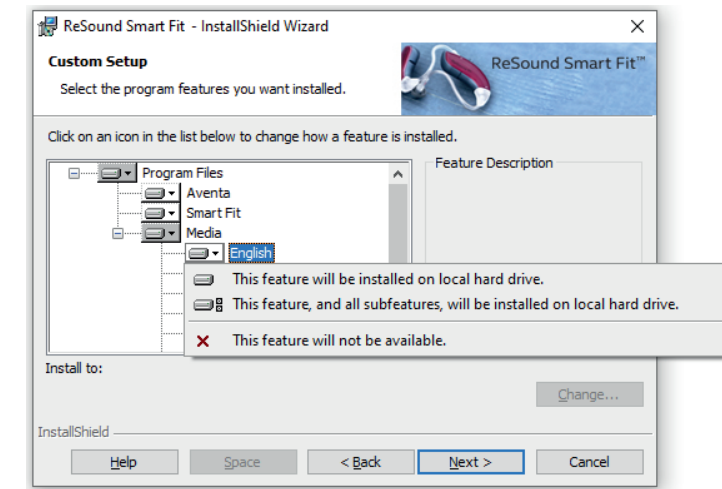
Installation steps



1. Start installing ReSound Smart Fit by clicking on Setup.
2. Select your preferred language for the installation wizard. Please note that this is not going to be the language of the software.

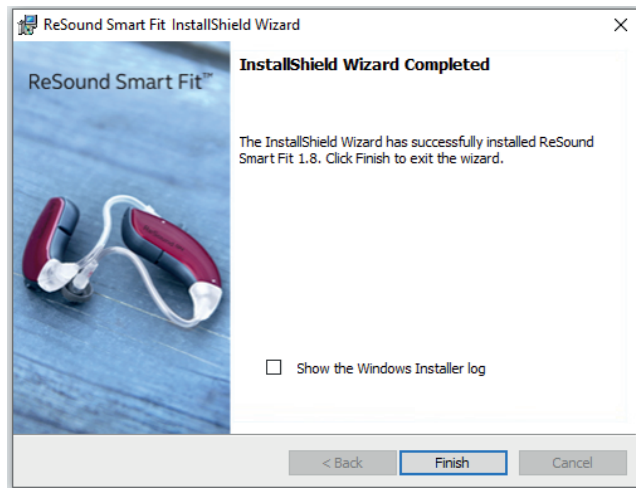


3. Click "Next" to proceed to "Market Selection". Select your country from the dropdown menu. Here you also have the option to enable or disable Standalone Installation, and Web Updates. Click "Next".



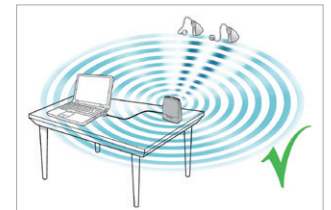
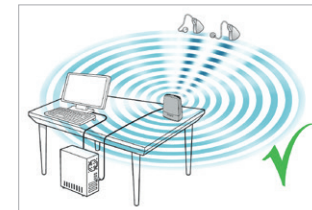
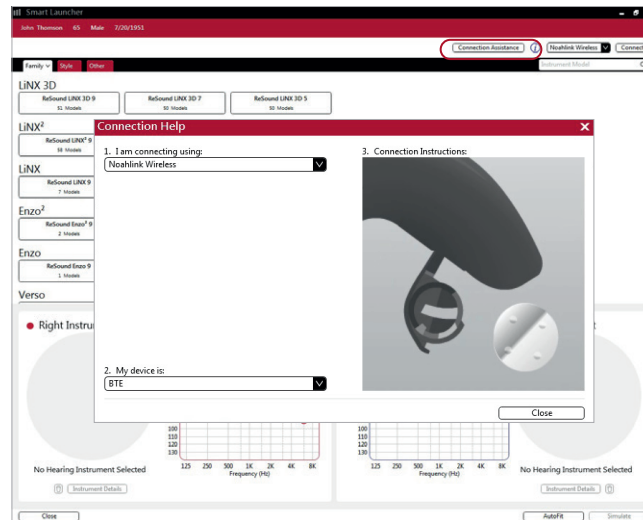
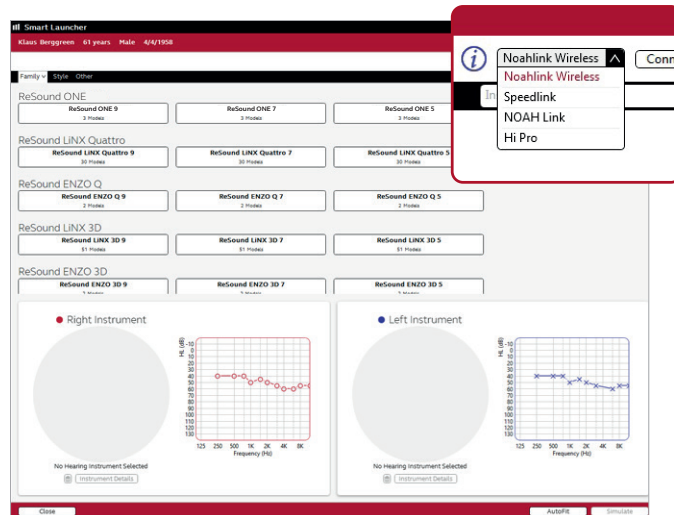
4. Relevant speech files are selected based on the selected market. Click "Next" to start the installation.

Note: Non-speech sound files are set as the default for markets without language-specific speech files.



5. Complete installation of ReSound Smart Fit by clicking "Finish".

Programming Interfaces



ReSound Smart Fit works with:

- NOAHlink Wireless
- Speedlink
- NOAHlink
- Hi-PRO

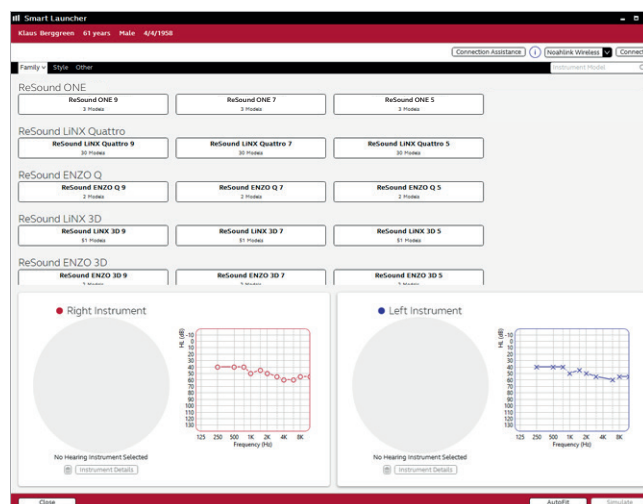
Select programming interface from the drop down menu in upper right corner of the screen.

Animations in “Connection Assistance” show how to connect specific models of hearing aids with the selected programming interface.

Noahlink Wireless placement:

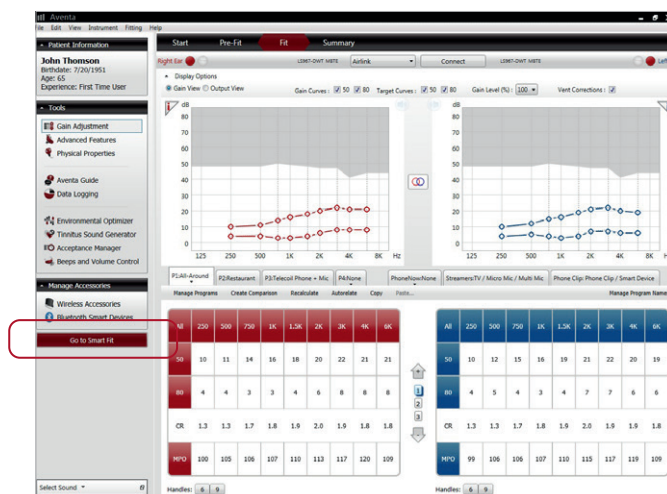
- Place Noahlink Wireless on the table with a clear line-of-sight to the hearing aids, which should be within a range of 10 feet (3 meters).
- Do not place Noahlink Wireless in a USB hub with other USB devices.
- When fitting hearing aids inside a sound booth, place the Noahlink Wireless inside or close to the booth.
- Do not use USB cables longer than 10 feet (3 meters) between Noahlink Wireless and the PC.

Good to know

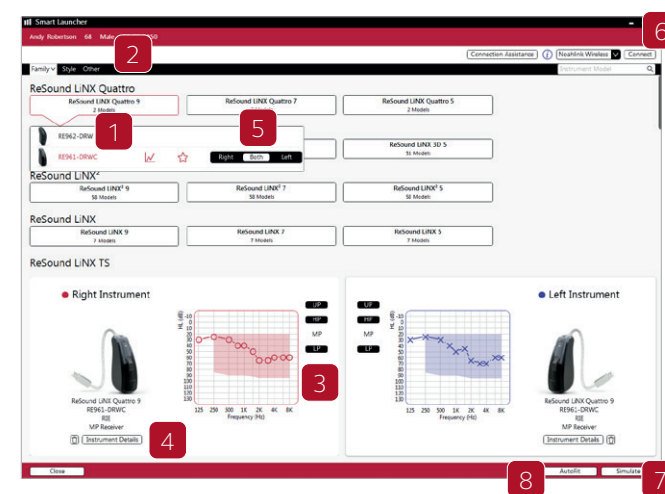


Smart Launcher

The Smart Launcher contains all of the product families found in both ReSound Smart Fit and ReSound Aventa fitting modules. The Smart Launcher automatically opens the fitting software module that supports the connected or simulated hearing aids.



NOTE: When you open a session previously saved with ReSound Aventa 3, or when you connect hearing aids previously programmed with it, you are automatically directed to the ReSound Aventa 3 fitting module. To upgrade your patient's existing ReSound hearing aids to the newest, go to Smart Launcher by clicking on the "Go to Smart Fit" button in the left side panel of ReSound Aventa 3.

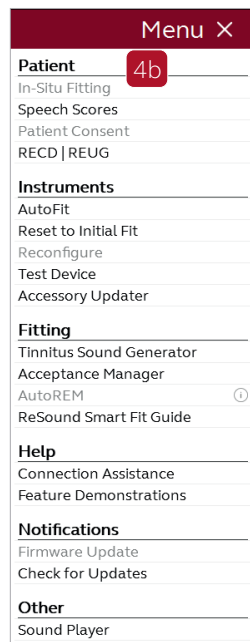
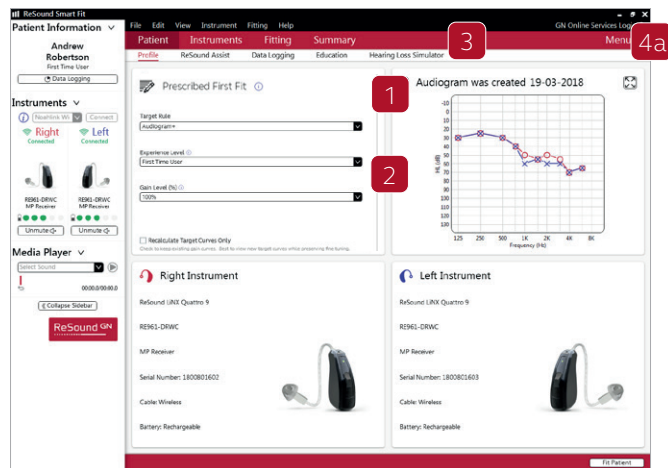


Product selection

1. Product family selection in Smart Launcher - here you can view all available products per family.
2. The "Aid Style" and "Other" tabs allow for filtering products based on their type or feature support. For example, "Based on Audiogram" shows only products with fitting ranges that suit your patient's individual audiogram.
3. Fitting range and patient audiogram.
4. Technical details of the selected hearing aids.
5. For simulation, select the hearing aids of the relevant ear(s). Connected hearing aids will be assigned as part of the connection flow.

To proceed to fitting with the selected aids, continue with one of the following options:

6. Connect
7. Simulate
8. Use "AutoFit" to be guided through the fitting steps.

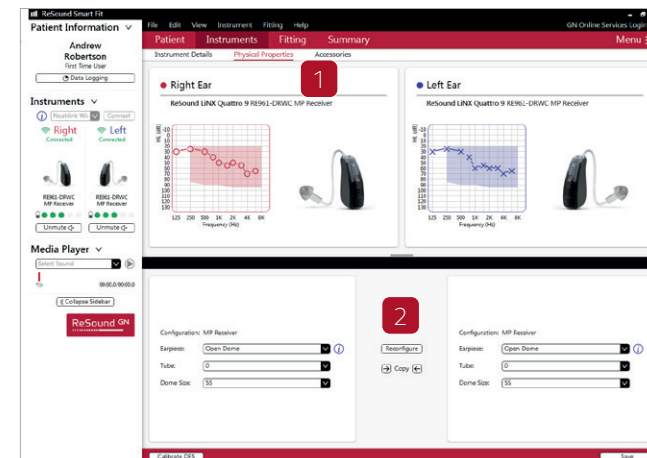


Patient screen

After launching ReSound Smart Fit you will see the “Patient” screen in the red ribbon on top.

1. For an optimized gain prescription, select the patient’s experience level with hearing aids based on the amplification history, on the “Profile” screen.
2. Select Experience Level based on patient’s previous experience with hearing aids. To reduce overall loudness, select “Gain Level (%)” for the prescribed target gains.
3. Demonstrate where the hearing aids can help the patient, by using the different “Audiogram Overlays” on the “Hearing Loss Simulator” screen.
4. To begin In-situ Fitting using the hearing aids:
 - a. Open “Menu”.
 - b. Select “In-Situ Fitting”.

⚠ WARNING: In-situ Fitting is not designed to take the place of diagnostic audiometry, and is a cross-check measure. In-situ Fitting only tests air conduction thresholds, and cannot account for conductive or mixed hearing losses. If inaccurate In-Situ Fitting measurements are applied to the fitting, gain could be set to levels that may damage residual hearing or exacerbate tinnitus and/or hyperacusis.



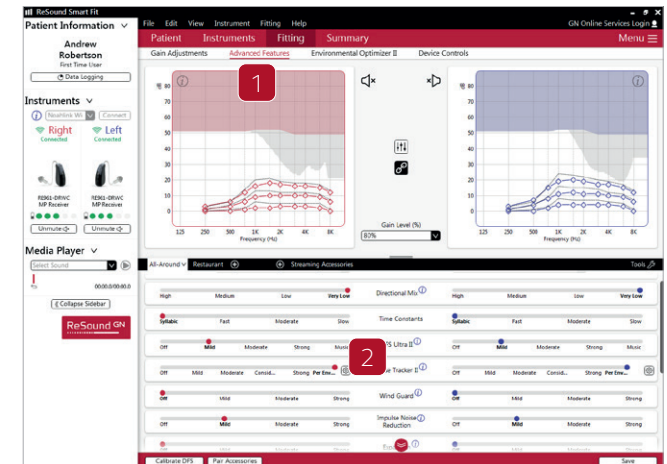
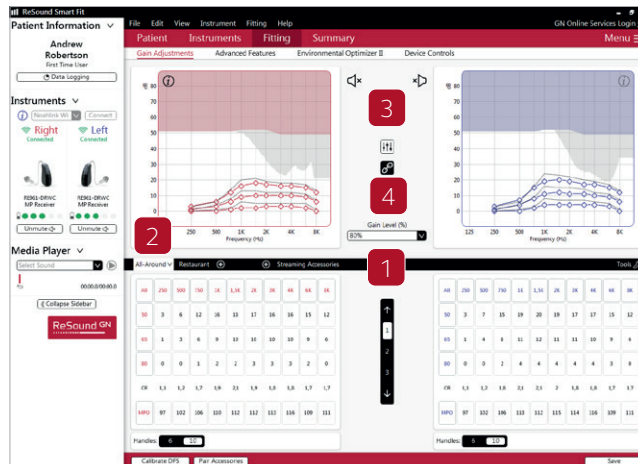
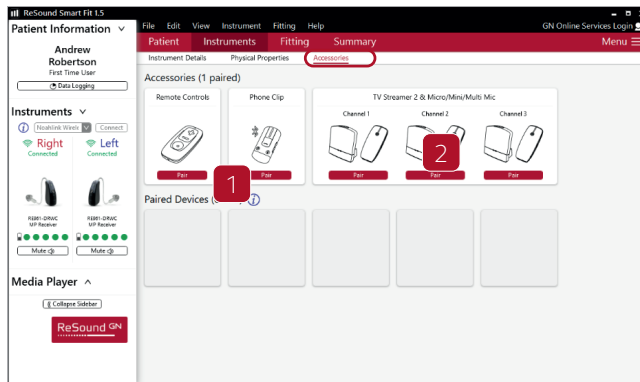
Instruments screen

Physical Properties

To reconfigure the hearing aids:

1. Select “Physical Properties” tab.
2. Select “Reconfigure”.

⚠ WARNING: If hearing aid earpiece is changed, care must be taken to ensure that the perceived loudness and sound pressure levels do not change when going from a more open earpiece to a more closed earpiece. an increased sound pressure level may damage residual hearing or exacerbate tinnitus and/or hyperacusis. DFS calibration should be performed after changing physical properties (e.g., earpiece type, receiver power). Changing hearing aid physical properties can impact insertion gains and occurrence of feedback which may damage residual hearing or exacerbate tinnitus and/or hyperacusis.



Caution: It is not recommended to perform DFS calibration under the following conditions:

- Incorrect insertion of the hearing aid
- Occluded ear canal due to earwax or other medical pathology
- If there is any physical damage to the hearing aid (including clogged receivers or sound bore, broken receivers, clogged microphones, etc.)
- If the patient is in a noisy environment

Performing DFS under the above conditions may result in increased DFS calibration output which may exacerbate tinnitus and/or hyperacusis.

Accessories

Select and pair accessories in “Accessories” tab. The screen can be accessed at the final step in the connection flow.

Click “Pair” beneath the accessory you wish to pair. When the accessory is successfully paired, the accessory image will appear in color with a remove button below it.

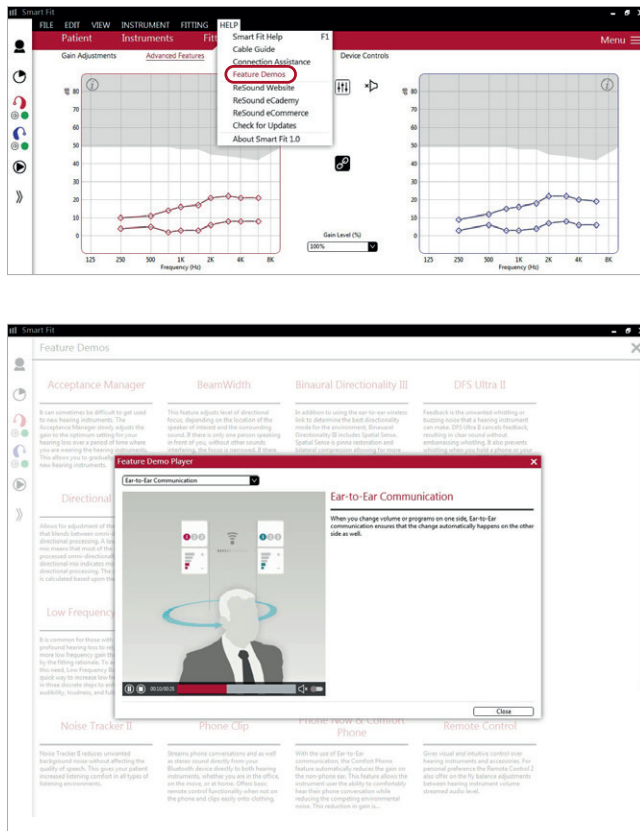
Fitting screen

Gain Adjustments

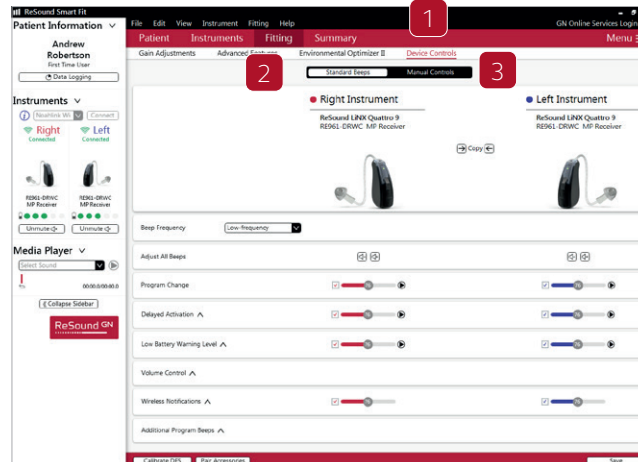
1. Adjust hearing aids gain by 1, 2, or 3 dB increments.
2. Select the program tabs to fine-tune gain settings.
3. Mute or unmute the hearing aids.
4. Link or unlink the hearing aids.

Advanced Features

1. Click “Advanced Features” to access features. These feature settings will apply to the currently selected program.
2. Navigate through each program to adjust these settings as needed.



“Feature Demonstrations” illustrate the features available in the hearing aids. You can find the animations by clicking on the ① next to each feature, or in the “Help” menu.



Device Controls

1. Adjust beeps and the volume settings by selecting “Device Controls”.
2. On the “Standard Beeps” tab, all the acoustic indicators can be demonstrated, enabled, adjusted or disabled as needed. Low or high frequency beeps can also be selected.
3. The “Manual Controls” tab has options such as customizing button functions, enabling and disabling the program button and adjusting the “Volume Control Range”. The Volume Control Range can enable the hearing care professional to configure the device to prevent the patient from increasing the volume or sound generator output level on the hearing aid by adjusting the High Range Volume to 0.

AutoREM

ReSound Smart Fit fitting software offers automatic real ear measurement (AutoREM) functionality. AutoREM is an integrated feature within ReSound Smart Fit so verifying hearing aid fittings with real ear equipment can be done within the software.

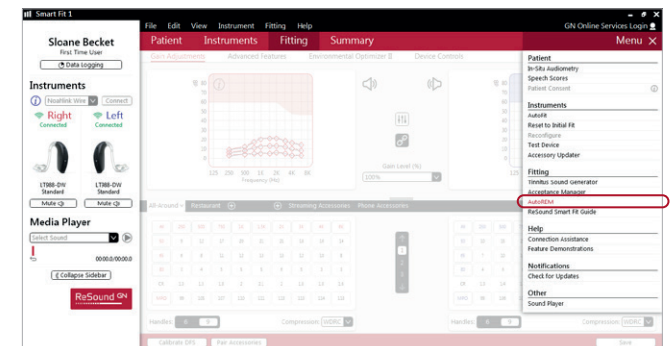
Gain is automatically adjusted at the time of the measurement. Once the measurements are completed, you can select having AutoREM apply the customized gain to the hearing aid programs for a more precise match to the prescriptive targets.

ReSound Smart Fit AutoREM offers:


- A selection to specify open fitting: This selection allows the measurement to account for the electroacoustic characteristics of an open fitting. Open fittings allow low frequency gain to escape the ear canal. Specifying an open fitting prevents ReSound Smart Fit from identifying the reduction of low frequency gain as unsuitable and, in turn, providing too much low frequency gain to try to correct the issue.

- A selection to specify the measurement program before performing REM: This allows the hearing care provider to select the program to use for the measurement within the AutoREM wizard, rather than using the active program upon entering the feature. This allows more flexibility without having to exit or restart the AutoREM wizard. The adjustments that result from measuring in the chosen program can then be applied to all fitted programs.
- Support for new test stimuli: New pure-tone and speech stimuli are included to allow for audibility assessment based on the goals of the test and varying protocols.

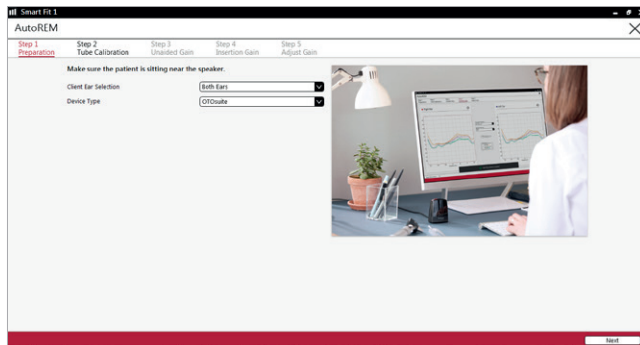
ReSound Smart Fit AutoREM functionality also offers integration of the Inter Module Communication protocol 2 (IMC2). IMC protocol 2 allows direct communication between ReSound Smart Fit and REM modules through Noah.



Verifying a fitting with AutoREM

The hearing aids must be connected in ReSound Smart Fit prior to opening the AutoREM wizard. AutoREM can be accessed from the hamburger menu  on the upper right side or through Fitting → Tools in the top menu.

Once in the AutoREM wizard, follow steps 1 through 5.



STEP 1: PREPARATION

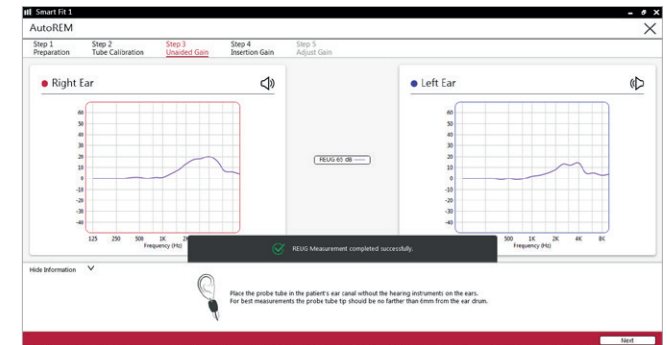
Select the ear to be measured and REM module to be used from the available menus. Use the Next button in the lower right of the screen to advance through the steps.



STEP 2: TUBE CALIBRATION

Prior to performing AutoREM measurements, probe tube calibration must be done. In order to complete probe tube calibration:

1. Place the module on the patient's ear while he or she is facing the speaker.
2. Fold the probe tube over and place the tube opening in front of the reference microphone.
3. Use the calibrate button in the center of the screen to begin the measurement.



STEP 3: UNAIDED GAIN MEASUREMENT

By measuring the sound pressure level of the open ear canal near the tympanic membrane, the real ear unaided gain (REUG) can be determined. The REUG is a measurement of the resonant peak of the patient's open ear without a hearing aid inserted. The resonant peak is the boost in high frequency sounds as a result of the combination of the pinna, the concha and, most influentially, the external ear canal. Each ear has its own unique resonant peak. When real ear measurements are not collected, we rely on an average resonant peak that may be very different from the patient's actual response. In short, the REUG is obtained in order to provide a reference for the real ear insertion gain (REIG) measurement used with several prescriptive formulas.

In order to complete REUG measurement:

1. Place the probe tube in the ear canal (without the hearing aid inserted) with the end of the tube at appropriate distance from the intertragal notch (i.e., within 5 mm of the eardrum).
2. Place the patient at appropriate distance and azimuth from the loudspeaker.
3. Click the REUG 65 dB button in the center of the screen.

The average adult will have a primary peak at around 2650 Hz with a secondary peak in the 4000 - 5000 Hz range¹, but this will vary according to the physical characteristics of the patient's ear.



Step 4: Insertion Gain Measurement

When a hearing aid or earmold is placed in the ear canal, the open ear gain is altered. Fitting prescriptive formulas attempt to compensate for the loss of natural gain by applying a certain amount of insertion gain. This requires measuring the sound pressure level of an input sound with the hearing aid inserted in the patient's ear. That measurement is used to determine the real ear-aided gain (REAG). The appropriate insertion gain is then calculated by subtracting the unaided gain (REUG) from the aided gain (REAG).

In order to complete REAG measurement:

1. Select:

A. Type of fitting, open or closed.

Open fitting selection should be used when a dome or mold with a large vent is coupled to the hearing aid.

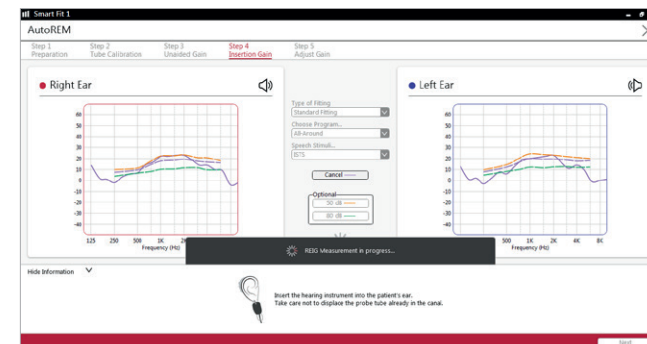
Use **closed fitting** for custom products or hearing aids coupled to earmolds with medium vents and smaller or no venting.

WARNING: Ensure that the fitting type matches the actual physical properties of the hearing aids. Performing AutoREM with a closed fitting selected may result in overamplification, if the hearing aid is coupled to an open earpiece. Overamplification may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

B. Program to be measured.

Any of the fitted programs can be used in addition to the REM program. The REM program is a simulated program that uses omnidirectional microphones, and all advanced features are set to off.

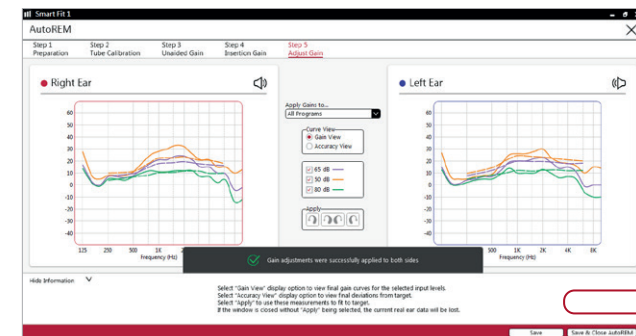
C. Stimulus to be used during the measurement.



WARNING: If speech-weighted noise is selected as a stimulus, turn off advanced features (e.g., noise reduction). It is also recommended to use the REM Test program when using speech-weighted noise stimulus. Advanced features may impact AutoREM measurement, and result in overamplification that may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

2. Place the hearing aid into the ear while keeping the probe tube in place.
3. Click the REIG 65 dB button in the center of the screen to start the measurement. The gain will be adjusted automatically to meet the target. Three attempts or fewer will be made.

Controls will be grayed out when the measurement is in progress.



This image shows the REIG measurement completed and the target automatically matched.

Optional: Additional measurements can be made at soft (50 dB) and loud (80 dB) input levels. All three input levels are adjusted during the initial 65 dB input measurement; therefore, those measured with soft and loud inputs will not be adjusted again.

Step 5: Apply Gain Adjustments

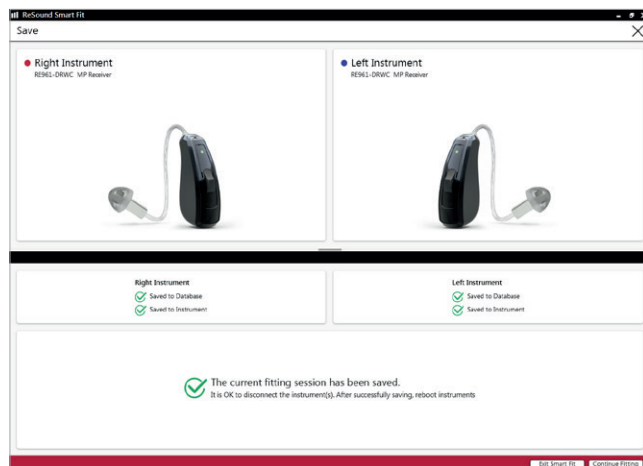
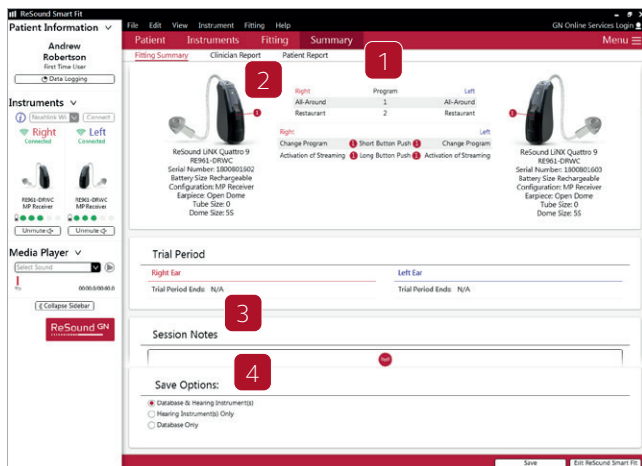
To apply the adjusted gain to the fitted settings:

1. Select the program(s) to apply the adjustments. Adjustments can be applied to all programs or to the one used for the measurement.
2. Select the ear to apply the adjustments. (This selection will immediately apply your changes. Afterwards, you will see a confirmation message.)

3. Select Save & Close AutoREM to return to the Fitting screen.

AutoREM streamlines the process of conducting real ear measurements (REM), making the process faster and more convenient. The automatic target-matching removes the variability of manually matching targets.

An internal study found that hearing care professionals spent less time verifying gain settings with AutoREM when compared with conventional REM.² Furthermore, the same study found less variability when targets were automatically adjusted versus manually adjusted. Patients will be fit with truly customized gain settings, adjusted for their ears, rather than relying on predetermined averages. These customized settings allow for a more accurate starting point for the fitting and potential for increased satisfaction. Ultimately, AutoREM provides a fast and reliable way to verify hearing aid settings, putting the patient on the road to a more positive amplification experience.



Summary screen

1. Confirm the number of programs.
2. Customize the “Clinician Report” and the “Patient Report”, which provides the patient with useful information.
3. Type in the notes that you want printed on the patient’s handout.
4. Save the fitting data using one of the options from “Save Options”.

You have now completed setting up the hearing aids.

ReSound Assist

This quick guide provides an overview to hearing care professionals (HCP), of how to perform a ReSound Assist fine-tuning with ReSound Smart Fit fitting software and the ReSound Smart 3D app. Please note that feature availability will vary by product family and technology level. Features shown in this guide may not apply to your selected product.



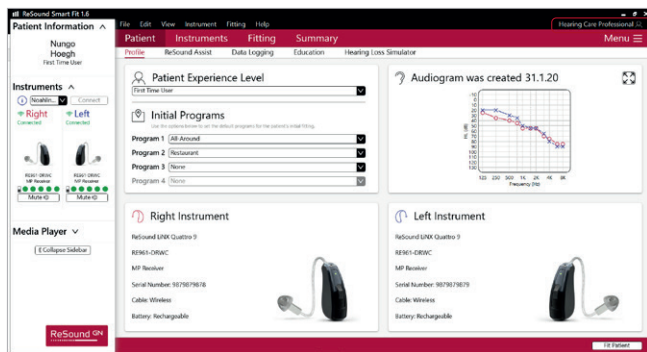
WARNING: Adjustment of the tinnitus sound generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the patient is a minor.

Use of the ReSound Assist feature for remote settings of the tinnitus sound generator, should only be performed by the parent or legal guardian in cases where the patient is a minor.

The patient shall discontinue use of the tinnitus sound generator and consult promptly with a licensed physician if one of the following conditions are experienced:

- a. Visible congenital or traumatic deformity of the ear.
- b. History of active drainage from the ear within the previous 90 days.
- c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
- d. Acute or chronic dizziness.
- e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- g. Pain or discomfort in the ear.

The patient shall discontinue use of the tinnitus sound generator and consult promptly with the hearing care professional if experiencing changes in tinnitus perception, discomfort or interrupted speech perception while using the tinnitus sound generator.



Getting started

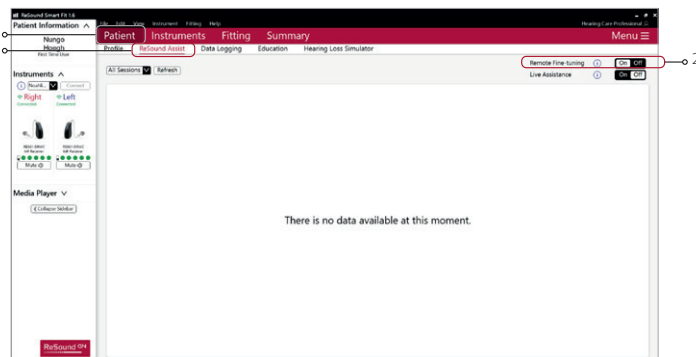
Connect hearing aids to the ReSound Smart Fit software. For further assistance, refer to the ReSound Fitting guide.

GN Online Services

In order to sign in:

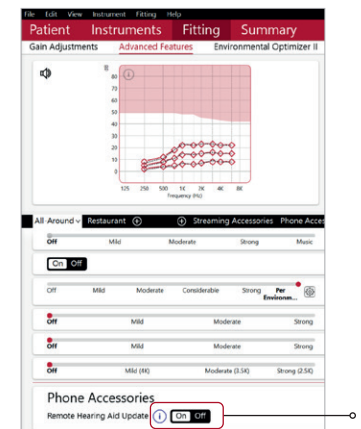
Enter your patientname and password to login to GN Online Services.

After login, your name will appear in the upper right corner of the fitting screen.




Activate remote fine-tuning

1. From the Patient screen, select ReSound Assist from the lower navigation row.
2. Click the 'On' toggle to activate remote fine-tuning.
3. To save the remote fine-tuning, complete the patient consent flow.



4. The default for Remote Hearing Aid Update is On. To turn it off, find the toggle on the Fitting Screen in Advanced Features.

 **Patient Consent Needed**
The sharing of health information requires patient consent. Review the document with the patient and Start Consent.

Cloud-enabled dispensers
Remote fine tuning of hearing instrument

Contact details of your hearing care professional:
Hearing Care Professional
GN RESOUND US - MISC SALES
8001 BLOOMINGTON FWY
BLOOMINGTON
MN 55420
US


Details of data protection officer (if any) at hearing care professional:
(Hereinafter "Hearing Care Professional" or "HCP")

Your Hearing Care Professional has sold you a hearing instrument produced by GN Hearing A/S, which is a Danish company with company reg. no. 55082715 and registered address at Laurupvej 7, 2750 Ballerup, Denmark (hereinafter "the Manufacturer").


To access all of the features included with your hearing instrument, you will need to activate GN Online Services. These services enable you to receive firmware updates, and enable your Hearing Care Professional to fine-tune your hearing device remotely at your request.

By activating the GN Online Services, you will be allowing your Hearing Care Professional and the Manufacturer to access and process information related to your hearing loss via these online services and the associated mobile app. This notice explains what information will be collected, and asks for your consent to process this information for the purposes stated below.

How do you intend to consent?

 Print Consent

Start Consent
Reject & Save

 **Patient Consent Needed**
The sharing of health information requires patient consent. Please click Agree to continue.

PART A CONSENT

Where you provide Part A Consent, you consent to your Hearing Care Professional and/or the Manufacturer (as specified) receiving and processing the following personal information about you in the manner, and for the purposes, detailed below which **IS NECESSARY** in order for the GN Online Services to be provided to you:


The following data categories are processed by the Manufacturer and HCP:

- **Your name and email address** : for the purpose of enabling fine-tuning and logging your consent.
- **Hearing threshold, hearing threshold shift, and other details regarding your hearing loss (health information)**: for the purpose of enabling fine tuning.
- **The length of time you use your hearing instrument** : for the purpose of enabling fine-tuning and optimizing your settings.
- **The hearing instrument's serial number, hardware identification number and software version** for the purposes of enabling fine-tuning and enabling firmware updates.
- **Fitting specifications and fitting type** : for the purpose of enabling fine tuning and optimizing your settings.
- **Hearing instrument settings**: for the purpose of enabling fine-tuning and optimizing your settings.
- **Information about the sound environment when sending a request via the app** : for the purpose of enabling fine tuning and optimizing your settings.

The following data categories are processed by the Manufacturer:

- **Device type information** : Generic device-specific information such as the type of mobile device and mobile operating system: for the purpose of optimizing your settings and providing customer services (questions, complaints, repair, etc).
- **Technical log information** : Technical information in server logs, e.g., details of how the apps are used, Internet protocol, device event information such as crashes, system activity, hardware settings, browser type, browser language, the date and time of your request

Reject & Save Previous **Agree**

 **Patient Consent Summary**
Please print and sign the document below. This should be kept in the Hearing Care Professional's records.

First Name: Last Name: Patient Email:

Cloud-enabled dispensers
Remote fine tuning of hearing instrument


Contact details of your hearing care professional:
Hearing Care Professional
GN RESOUND US - MISC SALES
8001 BLOOMINGTON FWY
BLOOMINGTON
MN 55420
US

Details of data protection officer (if any) at hearing care professional:
(Hereinafter "Hearing Care Professional" or "HCP")

Your Hearing Care Professional has sold you a hearing instrument produced by GN Hearing A/S, which is a Danish company with company reg. no. 55082715 and registered address at Laurupvej 7, 2750 Ballerup, Denmark (hereinafter "the Manufacturer").

To access all of the features included with your hearing instrument, you will need to activate GN Online Services. These services enable you to receive firmware updates, and enable your Hearing Care Professional to fine-tune your hearing device remotely at your request.

By activating the GN Online Services, you will be allowing your Hearing Care Professional and the Manufacturer to access and process information related to your hearing loss via these online services and the associated mobile app. This notice explains what information will be collected, and asks for your consent to process this information for the purposes stated below.

 Print Consent

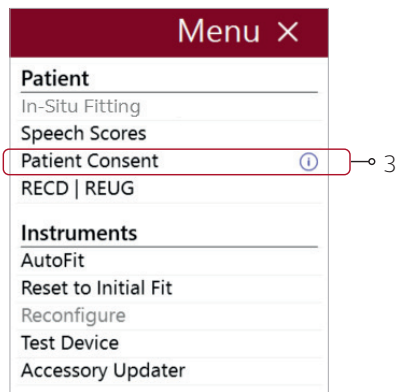
Continue
Reject & Save

Activate consent

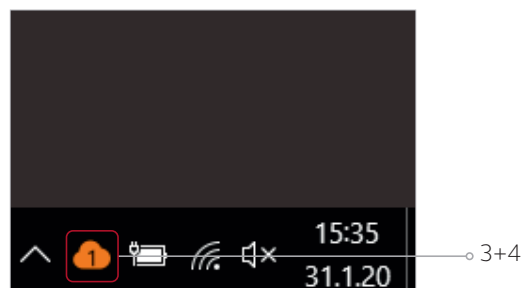
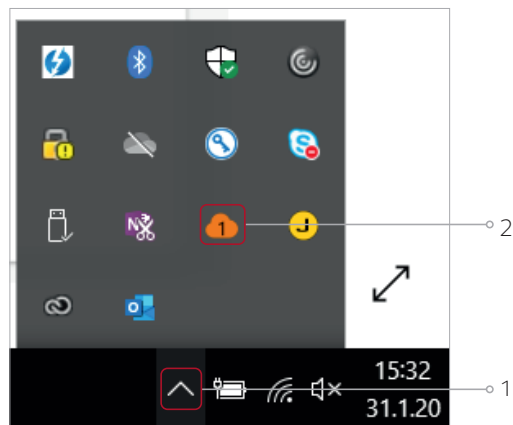
1. Click "Start Consent"

2. Click "Agree" on each of the pages of the consent process.

3. Enter the patient's name and email address for the consent to be sent via email. Should the patient not have an email address, your email address may be used. Use the "Print Consent" button to print a copy for the patient. It is also advised that a signed copy be kept in the patient's record.



It is also possible to complete the Patient Consent process during the session, by finding the option in Menu.



Move the cloud icon to the taskbar

The orange cloud icon should be visible in the taskbar so that you will know when requests for assistance are received.

1. Click on the upward arrow in the taskbar in order to view the hidden icons.
2. A window will appear containing the orange cloud icon for GN Online Services.
3. Click and drag the cloud icon to the taskbar.
4. The cloud icon will now appear in the taskbar as shown.

Sending an Assistance Request from the ReSound Smart 3D app

A patient wearing ReSound Smart Hearing aids with Remote Fine-tuning activated will be able to send an Assistance Request from the ReSound Smart 3D app. The following steps outline this procedure.

Assistance Request initiated

1. The patient clicks the “My ReSound” button.
2. “Request Assistance” is selected
3. An overview of the Assistance Procedure is shown.
4. Click on Start to initiate the request.
5. Questions are asked about the hearing and hearing aid status.
6. Choices are presented for possible sound quality complaints.

My ReSound

HEARING AID

Find my hearing aid

LEARNING

Learn about the app >

Guiding tips >

RESOUND ASSIST

Request assistance

My requests and new settings

Hearing aid software updates

Home Connectivity **My ReSound** More

Request assistance

DO YOU NEED HELP WITH YOUR HEARING AID SETTINGS?

Reach out to your hearing care professional right here. All you need to do is:

Define the problem and send a request.

Your hearing care professional creates and sends updated settings.

You receive and install the new settings on your hearing aids.

Start

Request assistance

BEFORE WE BEGIN

To check if we can help you with this service, please tell us if you're experiencing any of the following:

Has your hearing changed? Yes No

Is your hearing aid broken or clogged with wax/debris? Yes No

Is there a problem with the fit of the hearing aids in your ears? Yes No

Next

Request assistance

DEFINE YOUR PROBLEM

Please check the problem(s) you are experiencing. Add your own description on the last page.

☐ Too loud

☐ Too soft

☐ Muffled, unclear

☐ Extra noise, whistling, static

☒ Too sharp, tinny, or shrill

☐ The sound fluctuates or cuts in and out

☐ Other

Previous **Next**

Assistance Request further defined

1. The patient identifies the environment or the specific types of sounds that are contributing to their problem.
2. The patient specifies the severity of the problem, which ear is affected, and in which program(s) the problem is experienced.

The first screen (labeled 1) is titled 'Request assistance' and asks 'WHEN IS IT OCCURRING?'. It includes a text input for a description and three radio button options: 'All the time', 'In certain environments', and 'With specific sounds'. The second screen (labeled 2) asks 'HOW SEVERE IS THE PROBLEM?' with three buttons: 'Slightly annoying', 'Annoying', and 'Hearing aid unusable'. It also asks 'WHICH SIDE IS THE PROBLEM ON?' with 'Left', 'Both', and 'Right' buttons, and 'WHICH PROGRAM(S)?' with 'All programs', 'All-Around', and 'Restaurant' buttons. The third screen (labeled 2) shows the same questions as the second screen but with the 'Both' side and 'Restaurant' program selected. Each screen has 'Previous' and 'Next' navigation buttons at the bottom.

Assistance Request is finalized and sent to HCP

1. A summary screen is shown, where the patient is able to review the details of the problem, as well as enter a title for the request and add a personal message.
2. The patient clicks “Send request” to send the assistance request to the hearing care provider.
3. A message appears in the app, confirming that the request was sent and displaying the auto-reply with expected response time previously created for your business in GN Online Services.

The fourth screen (labeled 1) is titled 'Request assistance' and shows a 'SUMMARY' of the request details. It includes a 'REQUEST TITLE' text input and a 'PERSONAL MESSAGE' text input. The fifth screen (labeled 3) is titled 'Request assistance' and shows a 'THANK YOU!' message from the hearing care professional, including the date '16 January 2017'. Each screen has 'Previous' and 'Send request' or 'Close' navigation buttons at the bottom.

Patient making adjustments in the ReSound Smart 3D app

Patients may make their own adjustments in the ReSound Smart 3D app.

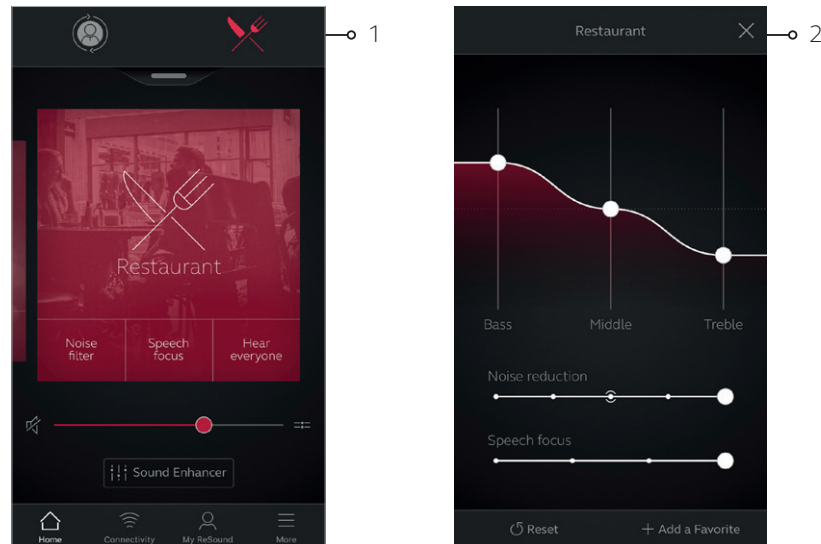
The tinnitus sound generator volume level, frequency shaping, white noise variation and Nature Sound can be adjusted by the patient, but the adjustments will be deleted upon rebooting the hearing aids, unless the settings are saved as a Favorite, which can later be accessed manually when re-opening the Smart 3D app.

The TSG volume can only be adjusted within the range set by the hearing care professional.

When rebooting the hearing aids, any adjustments will be deleted and default back to the settings performed by the hearing care professional.

Permanent adjustments to the default settings can be requested using ReSound Assist Live. If the HCP agrees and makes a permanent adjustment to a default setting, the new default setting will be downloaded.

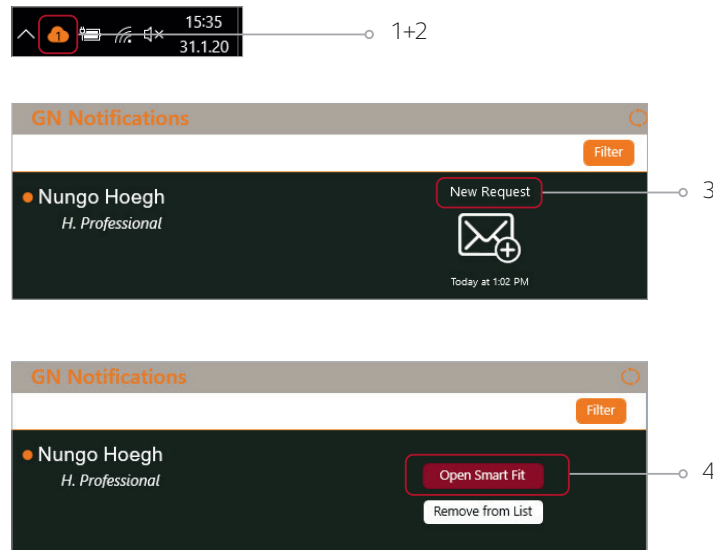
1. In this example, the patient makes adjustments to the Restaurant program.
2. The patient uses the Sound Enhancer feature to increase low frequencies (Bass) and reduce high frequencies (Treble) in restaurant environments. The patient has also set the Noise Reduction to Strong.
3. The patient finds the sound quality of the adjustment to be beneficial and wishes to make a permanent change to the Restaurant program to incorporate these changes.



Receiving an assistance request from a patient

Notification of assistance request

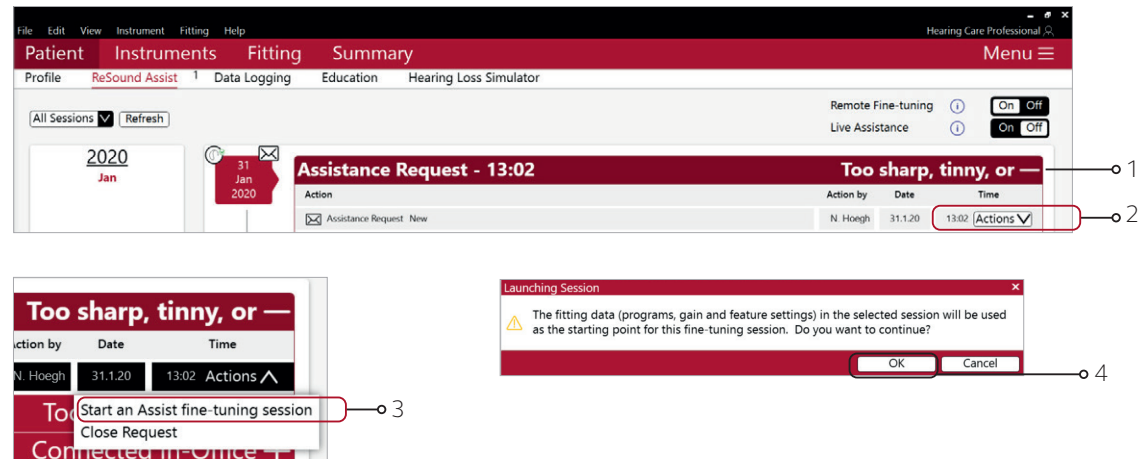
1. The number of requests received will appear in the cloud icon in the taskbar.
2. Click on the cloud icon to open the GN Notifications box. A list will appear if more than one request is received.
3. Click on “New Request”. The options “Open Smart Fit” or “Remove from List” will appear.
4. If “Remove from List” is selected, the request is deleted from the Notification Tray, but will still appear on Patient’s Timeline in ReSound Smart Fit.
5. Click on “Open Smart Fit” to go directly to the timeline within ReSound Assist for that particular patient.



You will also automatically receive email notifications for Assist requests. To change settings for email notification, go to the Email Preferences under your profile menu in the GN Online Services portal.

Starting an Assist fine-tuning session from the timeline

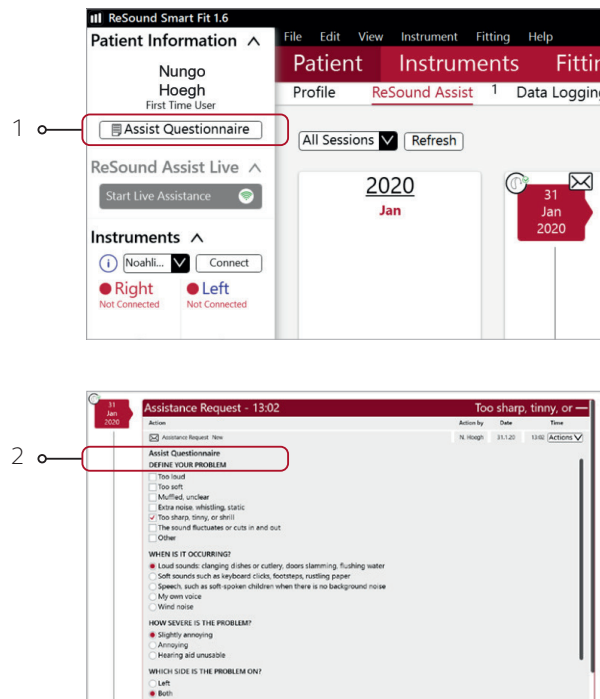
1. The assistance request will now appear on the patient's timeline in the ReSound Assist screen.
2. Click on "Actions" to select the either "Start an Assist fine-tuning session" or "Close Request".
3. Click "Start an Assist fine-tuning session".
4. A pop-up message will appear stating that the selected session will be used as the starting point for the Assist session. Click "OK" to continue.



View patient's Assist questionnaire

There are two ways in which the Assist Questionnaire sent by the patient from the ReSound Smart 3D app can be viewed:

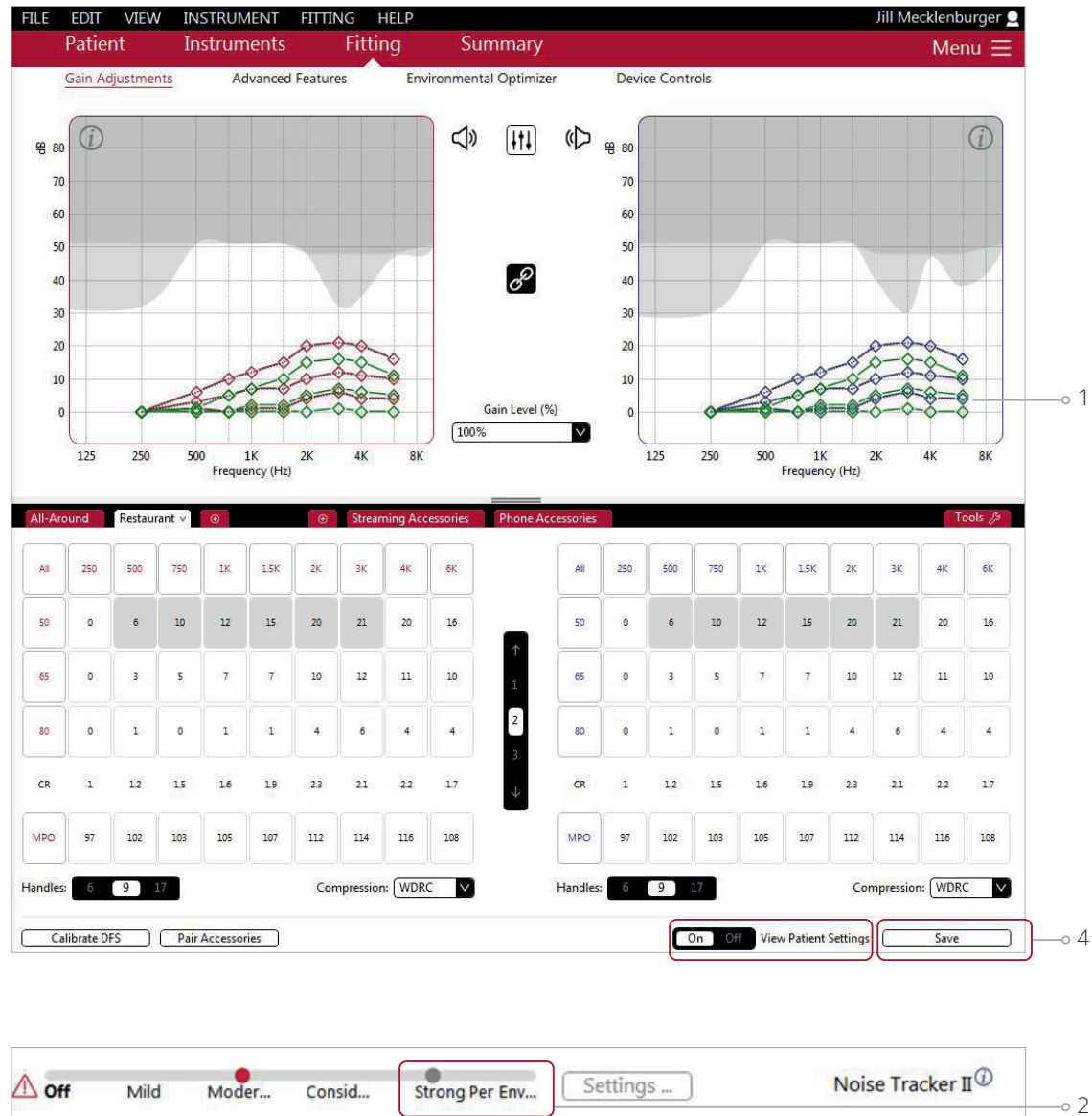
1. Click the "Assist Questionnaire" box beneath the Data Logging box in the sidebar. This will expand the questionnaire and enable it to be moved around the fit screen during fine-tuning adjustments.
2. Click "Assist Questionnaire", which will appear after "Message from patient" in the Assistance Request on the Timeline. This will expand the questionnaire for viewing.



View the patient's preferred settings

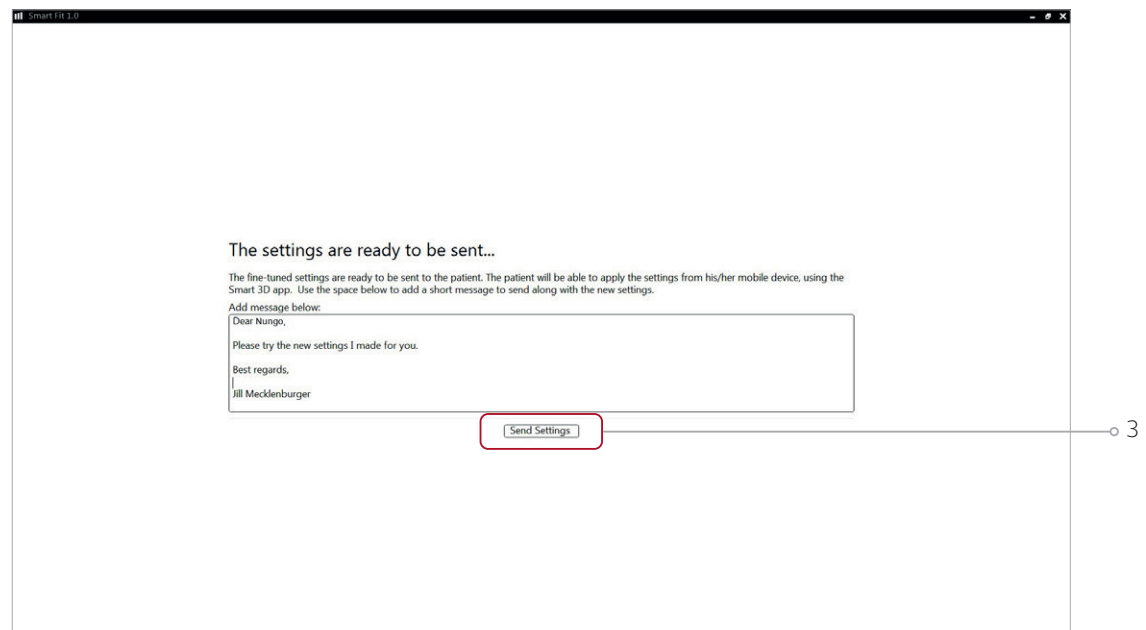
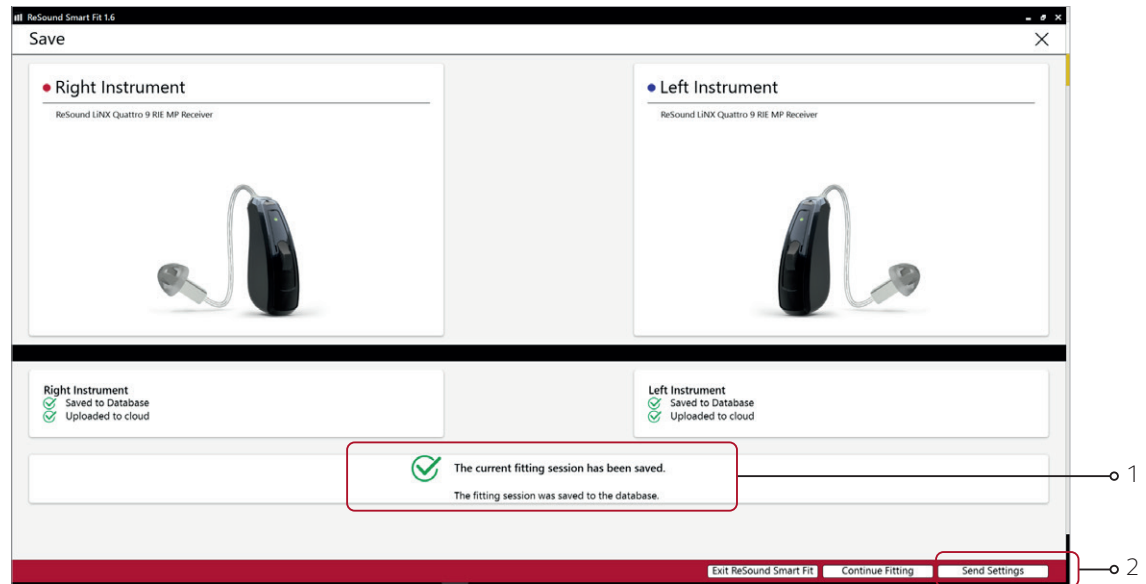
Click the “On” toggle for View Patient Settings at the bottom of the Fitting screen. This will enable viewing of the patient's preferred adjustments to settings in the app.

1. On the Gain Adjustments screen, patient settings are represented as green symbols.
2. On the Advanced Features screen, patient settings are represented as grey dots on the settings.
3. Fitting adjustments can be made from this information as well as from the Assist Questionnaire. (See “View Patient's Assist Questionnaire” on the previous page)
4. After making necessary adjustments, click “Save” in the lower right corner of the Fitting Screen.



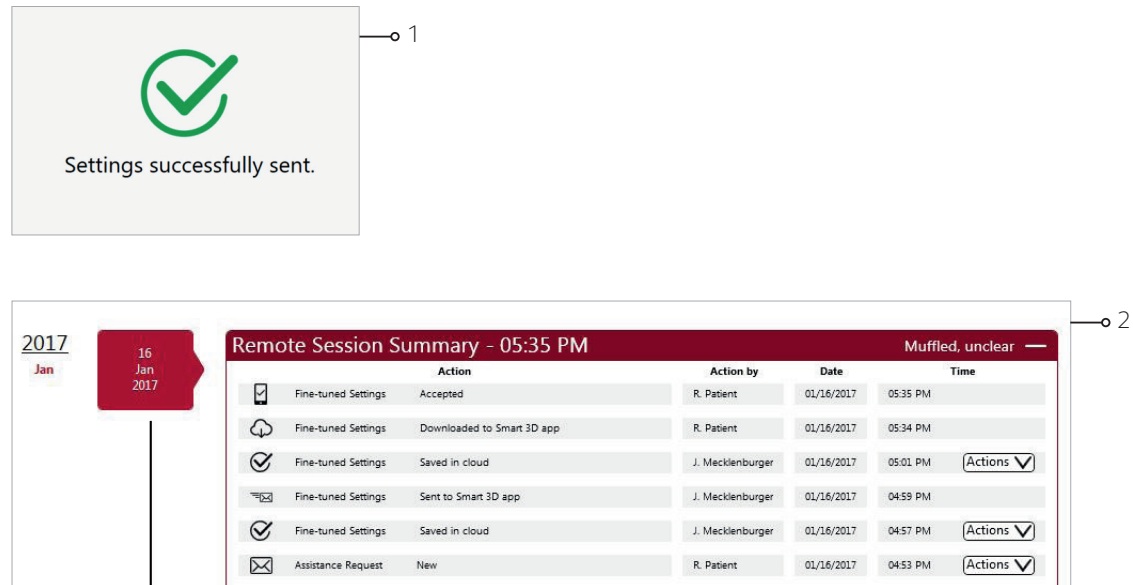
Save and send package

1. After saving on the Fitting screen, a message will appear stating that the current fitting session has been saved.
2. Click “Send Settings” in the lower right corner.
3. A free text screen will appear. This allows you to compose a message to the patient. A summary of the changes made can be included if desired. Click “Send Settings” again.



Confirmation of settings sent

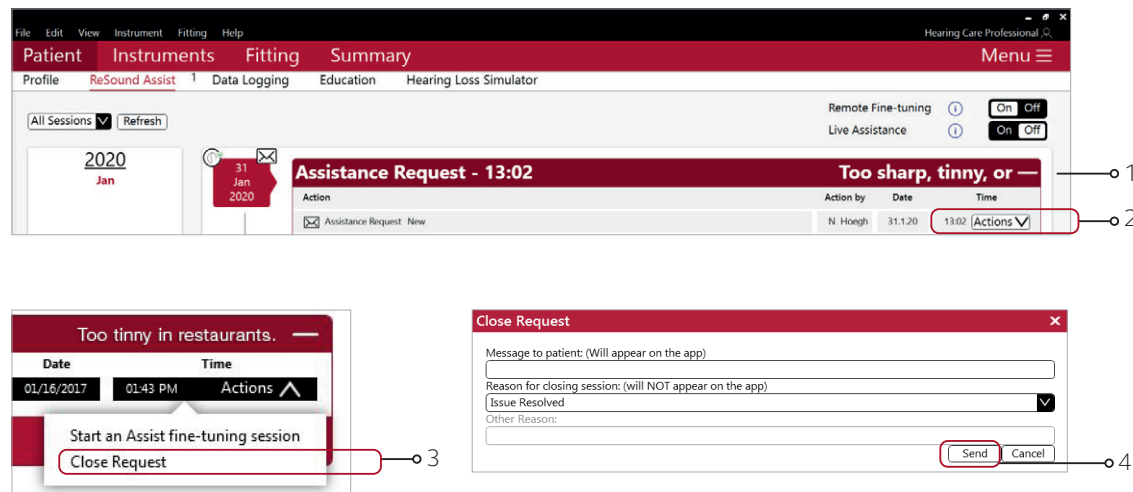
1. After sending the newly adjusted settings back to the patient, a message will appear stating “Settings successfully sent”.
2. A summary of the actions taken can be viewed on the patient timeline.



Closing the Assistance Request

After sending the package, go to the patient timeline to close the request. The patient has a maximum of 5 open requests in the ReSound Smart 3D app and only you can close them.

1. Go to the Assistance Request on the patient's timeline.
2. Click on “Actions” to select the either “Start an Assist fine-tuning session” or “Close Request”.
3. Click on “Close Request”.
4. Enter a message for the patient and a reason for closing the request. Click on “Send”.



You also have the option to close requests from the Patients section in GN Online Services at <https://portal.gnonlineservices.com>.

Sending a remote fine-tuning without an Assistance Request

You can send a remote fine-tuning to a patient without having received an Assistance Request.

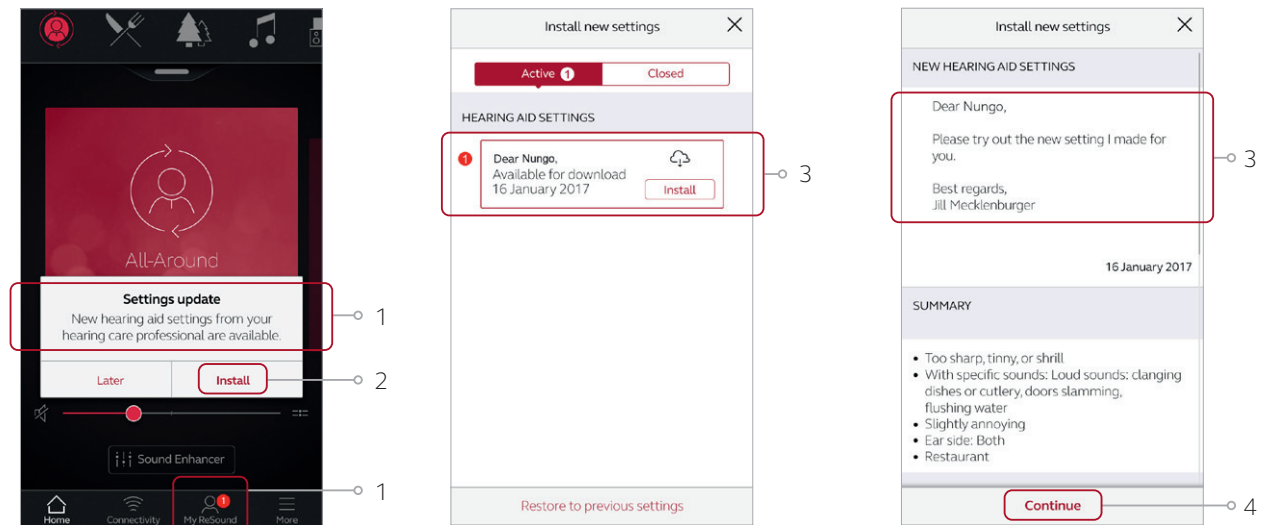
1. Pull up the patient on the fitting screen.
2. Ensure login to GN Online Services.
3. Follow the standard fitting flow.
4. Save the fitting.
5. Choose “Send Settings” on the Save screen.

The patient will receive the package in the ReSound Smart 3D app, and the Remote Session will appear on the patient’s timeline.

Receiving fine-tuned settings from the HCP

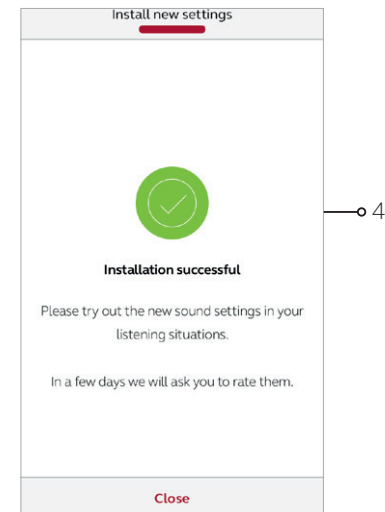
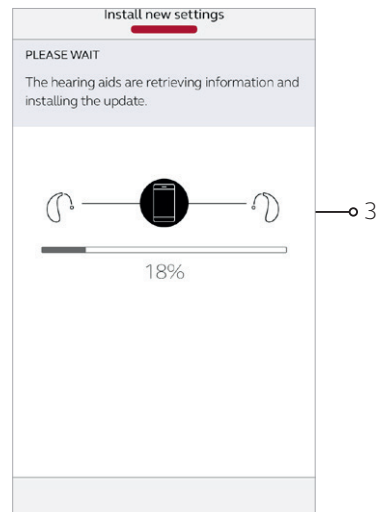
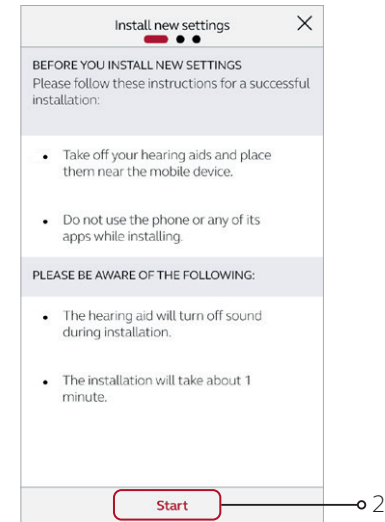
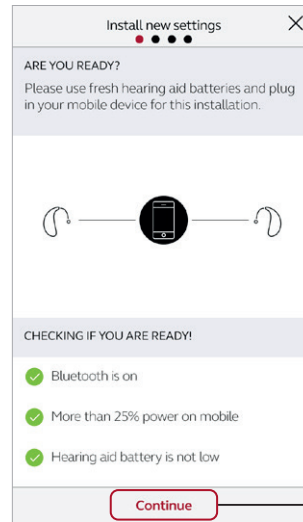
Fine-tuned settings received in the ReSound Smart 3D app

1. A notification will appear in the ReSound Smart 3D app and a notification badge will be visible on the “My ReSound” icon.
2. Click “Install” on the notification. In the “Active” list, the new settings available for installation will appear at the top.
3. Click “Install”. The app displays the message included in the settings.
4. Click “Continue”.



Installing fine-tuned settings in ReSound Smart hearing aids

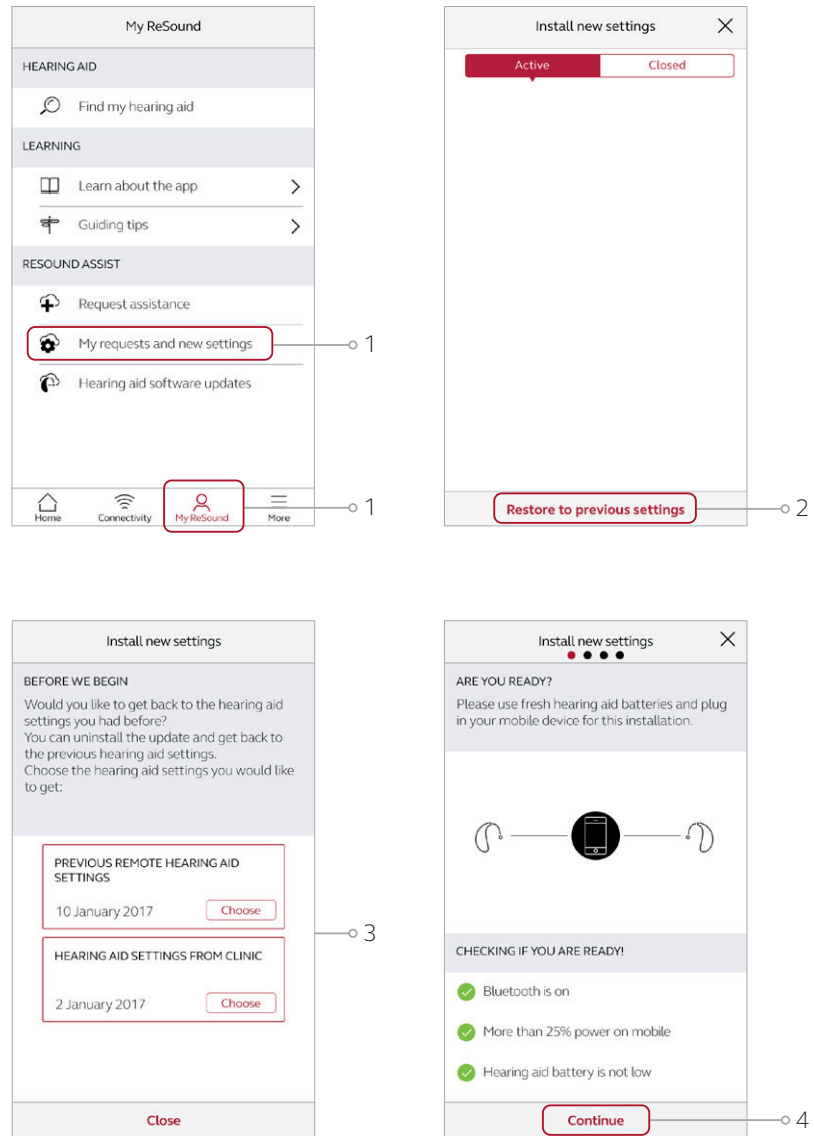
1. The app checks battery and Bluetooth status before starting installation. Click “Continue”.
2. Items to be aware of before the installation starts. Click “Start”.
3. A progress bar will appear to show the status of the settings being updated.
4. Finally, a message stating “Installation Complete” confirms that the fine-tuned settings have been uploaded to the hearing aids.



Restoring previous settings in ReSound Smart hearing aids

The patient can go back to the settings that were prior to installation of the new fine-tuned settings. The patient can choose between the latest fine-tuning sent remotely or the latest fitting done in the office.

1. Click “My ReSound”. Then click “My Requests and New Settings”.
2. Click “Restore to Previous Settings”.
3. Choose whether to restore previous settings sent remotely or those fitted in the office.
4. Follow the installation flow as before.



ReSound Assist Live



WARNING: ReSound Assist feature cannot identify if hearing aids are damaged or clogged with wax or debris. Adjustments to damaged hearing aids may result in gain levels that can damage residual hearing or exacerbate tinnitus and/or hyperacusis.

ReSound Assist cannot identify pathologies of the ear canal, or perform diagnostics of hearing aids for damage, ear wax, or debris. Incomplete evaluation of patient or failure to inspect hearing aids can result in changes via ReSound Assist leading to gain levels that can damage residual hearing, or exacerbate tinnitus and/or hyperacusis.

The use of Live Assistance shall be discontinued and the patient should be referred to a licensed physician if it is suspected that one of the following conditions are present:

- a. Visible congenital or traumatic deformity of the ear.
- b. History of active drainage from the ear within the previous 90 days.
- c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
- d. Acute or chronic dizziness.
- e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- g. Pain or discomfort in the ear.



CAUTION: Live Assistance should only be performed under the supervision of the parent or legal guardian in cases where the patient is a minor. If misuse occurs, this may lead to gain levels that can damage residual hearing or exacerbate tinnitus and/or hyperacusis.

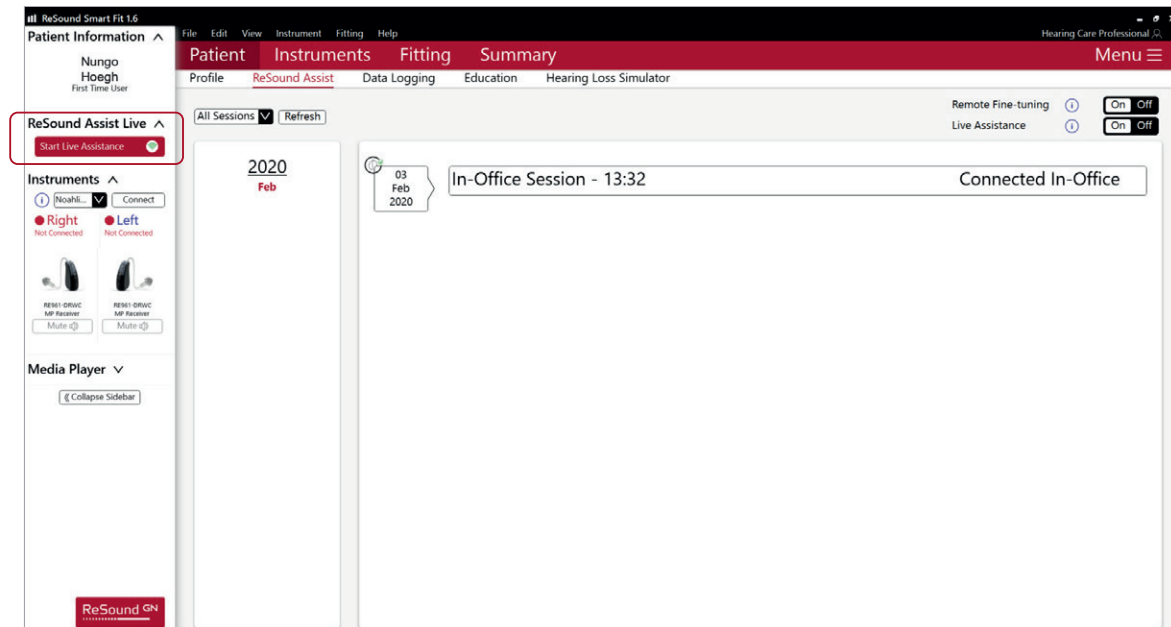
The use of ReSound Assist shall be discontinued and replaced with a face-to-face fitting if one of the following conditions are present:

- Feedback due to earwax
- No sound or reduced output from hearing aids due to clogged receivers or sound bore
- No sound or reduced output from hearing aids due to broken receivers
- No sound or reduced output due to clogged microphones
- Failure to adhere to the above may lead to adjustment of gain levels that can damage residual hearing or exacerbate tinnitus and/or hyperacusis.

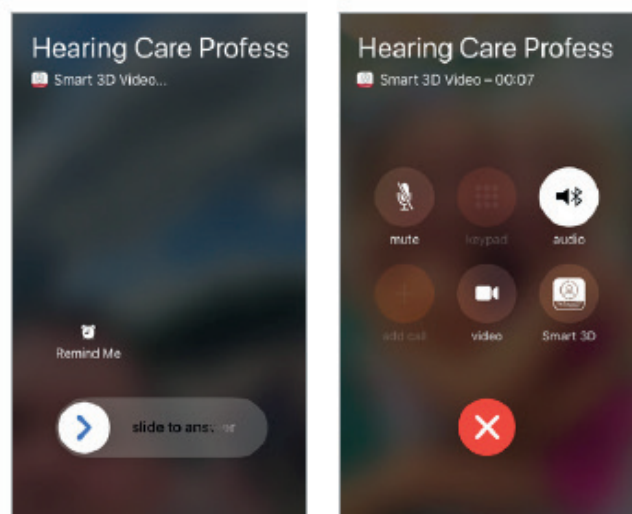
ReSound Assist Live functionality is not enabled by default. For more information about access, please contact your local GN ReSound representative.

Initiate the call

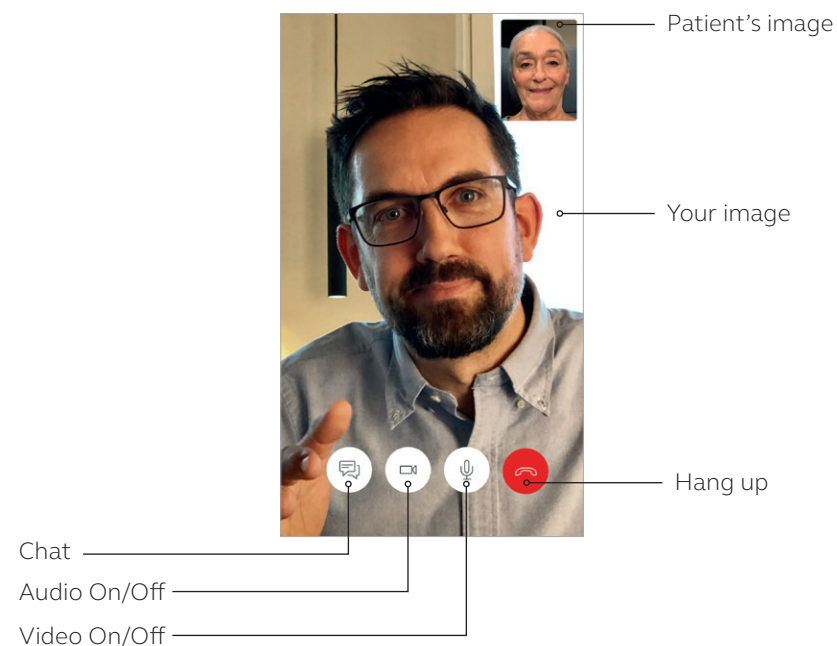
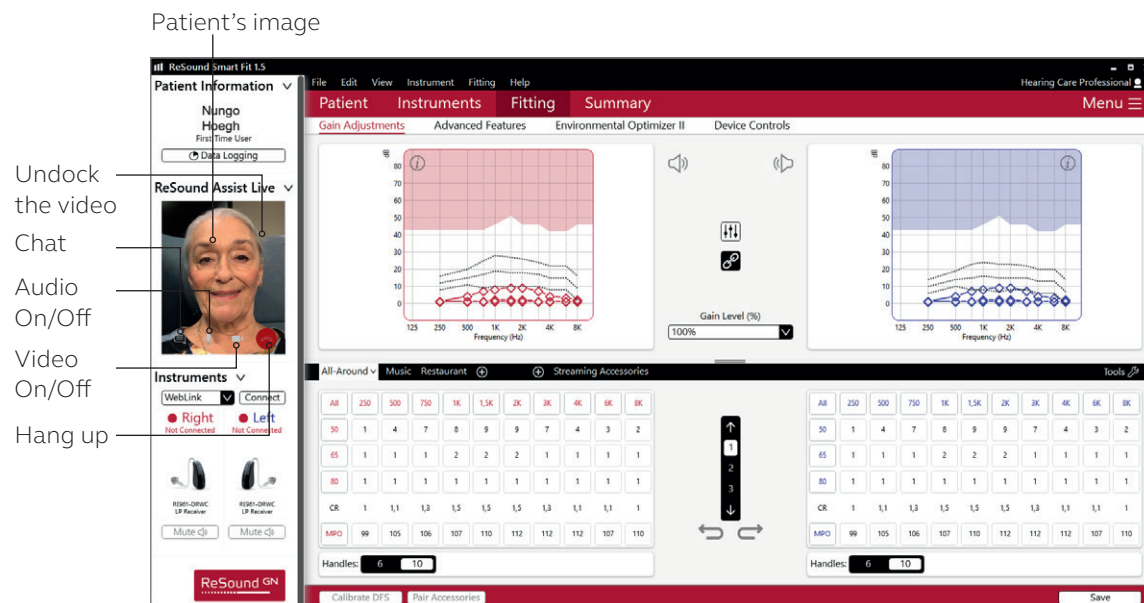
- Turn on Live Assistance toggle on the ReSound Assist screen.
- The patient must have the hearing aids paired with a smart phone with the ReSound Smart 3D app installed. It is not necessary to have the app open to receive the call.
- Start up the fitting software in simulation, following the same first steps as in ReSound Assist remote fine-tuning.
- Log in by using ReSound Assist credentials, if not already done.
- Click on the “Start Live Assistance” button to initiate the call with the patient. This will initiate ringing on patient’s mobile device without further warnings.



NOTE: If you are using ReSound Assist Live for remote fitting, please see the sections with additional guidance for Remote Fitting, and Remote Fitting Using In-Situ Testing in this guide.



You can start the conversation as soon as the patient answers your call. The patient can start the video call, by clicking on either video or Smart 3D. During the call both you and your patient can click on the relevant icons to enable or disable audio and/or video, initiate a chat, or hang up.



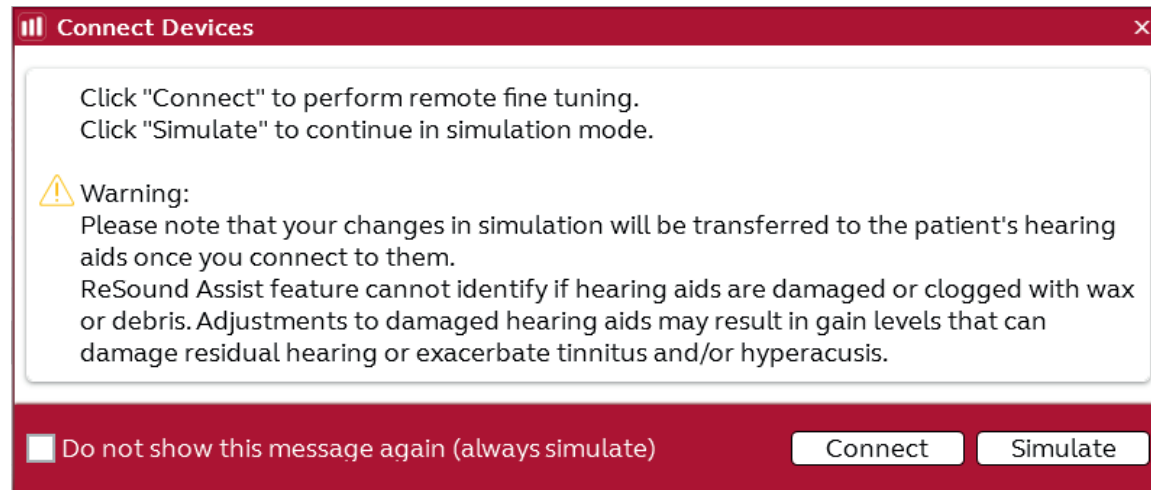
Perform ReSound Assist Live fine-tuning

To connect to hearing aids click on “Connect” on the prompt you will see in the fitting software.

If you choose to simulate in the above prompt, you still can connect to the hearing aids in the panel on the left side of the screen. Please note that your changes in simulation will be transferred to the patient’s hearing aids once you connect to them.

The patient will hear your voice through the hearing aids until the hearing aids are connected to fitting software. Throughout the connection, your patient will hear your voice through the phone’s speaker instead of the hearing aids.

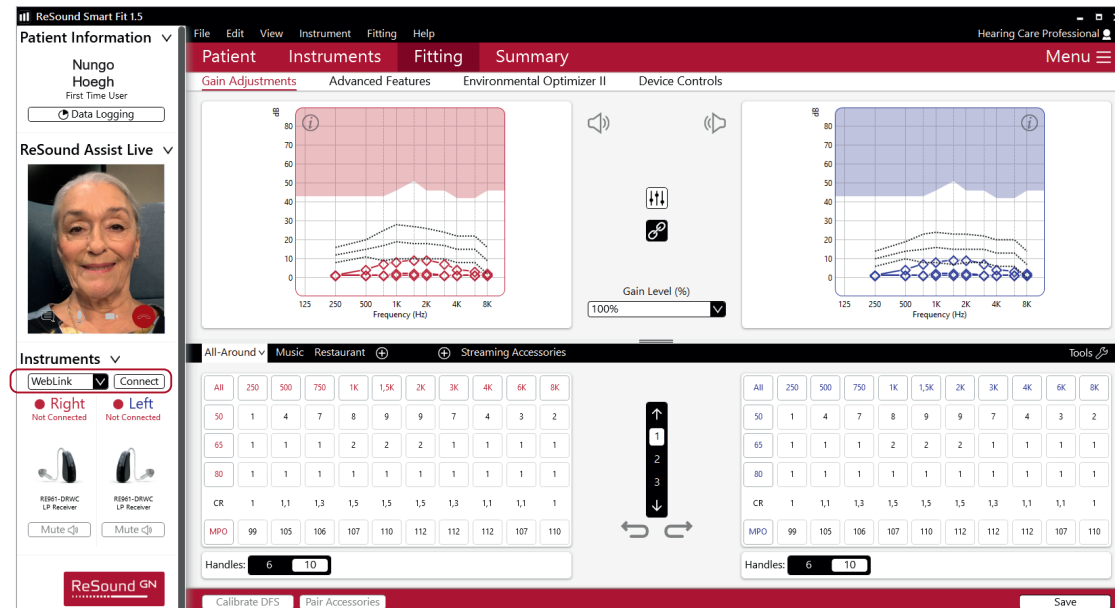
Note - The programming interface for Live Assistance is Weblink, but it is required to have Noahlink Wireless plugged in.



Continue with your fine-tuning. Your patient will hear the adjustments in the hearing aids live and can provide feedback right away. Your patient will still hear you through the phone's speaker.

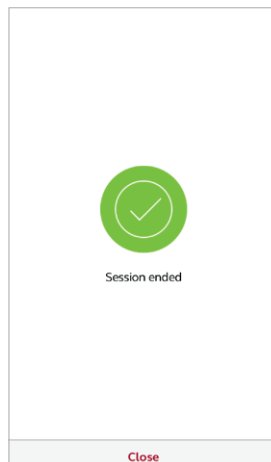
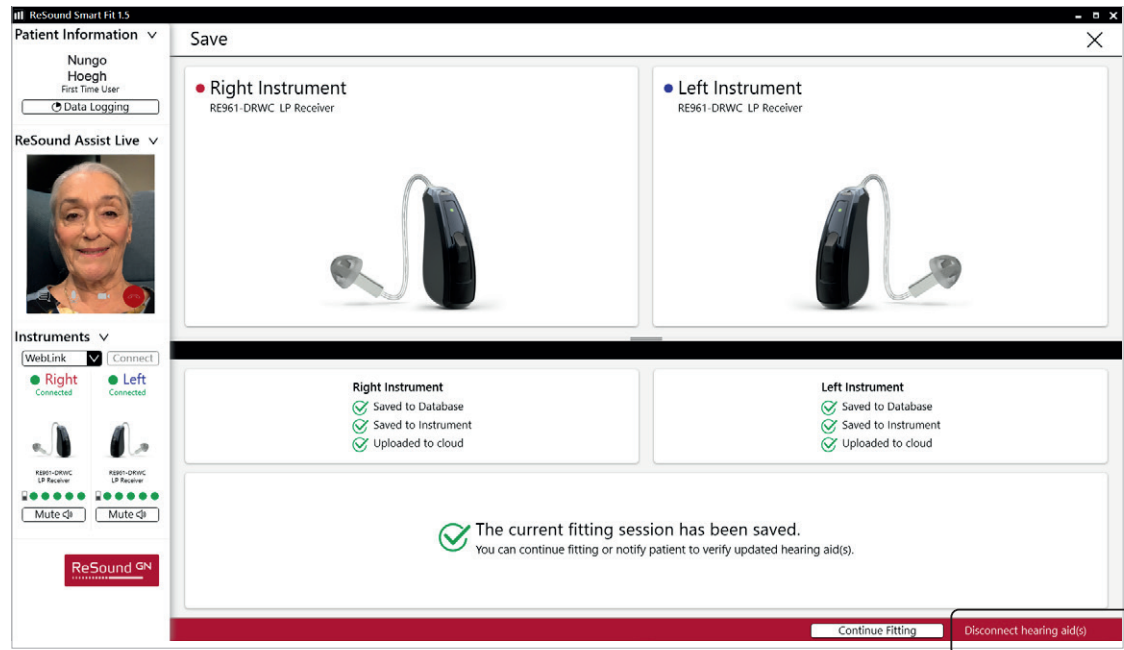
These features are disabled in Live Assistance sessions:

- Pairing Accessories
- AutoFit
- AutoREM
- Change Instruments
- Firmware Update
- Restore Instruments
- Test device



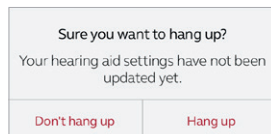
Once done, save the fine-tuning.

To apply the fine-tuning to your patient's hearing aids, click "Disconnect hearing aids. This will reboot your patient's hearing aids without requiring the patient to take any action. Once done, the hearing aids are disconnected from the fitting software. If you want to make further adjustments after disconnecting the hearing aids, you can connect to the hearing aids again in the same session.

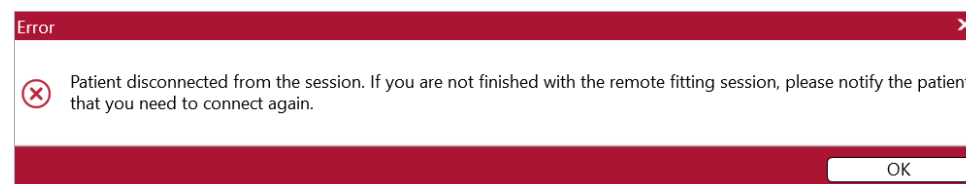


The Live Assistance session ends when you end the call with your patient. Your patient will be notified about this on the app.

Note - If the patient attempts to end the call, he/she will first see the prompt below on their phone.



If the patient ends the call by choosing Hang Up, you will be notified with this prompt in fitting software.



Additional guidance for remote fitting

The following guidance is recommended when you perform a remote fitting of a new hearing aid using ReSound Assist Live (Live Assistance). The guidance is designed to ensure the fit's accuracy and the patient's safety.


The Live Assistance appointment should be treated exactly as a normal in-office hearing aid fitting. All normal procedures conducted at these visits should be conducted through Live Assistance.


Please note:


- This guidance assumes that national as well as other regulations and guidance for hearing aid fitting are followed, e.g., medical evaluation, reimbursement regulation, etc.
- For the US: Please ensure that you remain familiar with and in compliance with federal, state and local rules and regulations applicable to your practice as they relate to remote fitting. Regulatory requirements in this area of practice are constantly evolving, including with regard to remote medical evaluations and the practice of remote care across state lines.
- This guidance is relevant only in the remote fitting cases where there is a valid audiogram for the patient on file. The patient can be a new patient or an existing hearing aid patient.
- If a valid audiogram does not exist on file for the patient, please refer to additional guidance for remote fitting using in-situ testing that follows.


Required software to enable Live Assistance:

- o Latest version of the ReSound Smart Fit fitting software.
- o Latest version of the ReSound Smart 3D app (v. 1.7.0 or newer)

 **WARNING:** Instructions provided in this document for choice of hearing aid style must be followed.

 **WARNING:** Tinnitus Sound Generator (TSG) cannot be activated for initial fittings via Live Assistance. Initial activation of TSG must take place at an in-office visit.

 **GENERAL WARNINGS:** Prior to shipment to user for remote fitting, hearing aids must be pre-programmed to the audiogram on file.

 **GENERAL PRECAUTIONS:**

- Domes can get detached and stuck in ear canal. If they are not removed in timely manner, it can cause damage to tissue in the ear canal.
- A receiver wire that is too short can cause skin irritation on top of the outer ear.

Overview of steps to take

1. Verify that a valid audiogram is on file for the patient.
2. Prepare your patient. Important: Consent for GN Online Services must be obtained.
3. Prepare the hearing aids: Fit and assemble the hearing aids before delivering them to your patient.
4. Prepare your Live Assistance setup.
5. Check that the patient is ready to receive the Live Assistance call: The ReSound Smart 3D app must be downloaded and connected to the hearing aids.
6. Conduct the Live Assistance call with the patient.
7. Follow-up meeting in the clinic.

APPENDIX A: How to obtain consent for GN Online Services from your patient

Overview of steps to take

1. Verify that a valid audiogram is on file for the patient.
2. Prepare your patient. Important: Consent for GN Online Services must be obtained.
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4. Prepare your Live Assistance setup.
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6. Conduct the Live Assistance call with the patient.
7. Follow-up meeting in the clinic.

APPENDIX A: How to obtain consent for GN Online Services from your patient

Hearing aid styles for remote fitting

Receiver-In-the-Ear (RIE) and Behind-the-Ear (BTE)

Step 1: Verify that a valid audiogram is on file for the patient

1. Retrieve the patient from the NOAH database and verify the validity of the audiogram. This should be done for both new and existing patients ¹.
 - a. If there is not a valid audiogram on file for the patient, please refer to this guidance: ReSound Assist Live – Additional guidance for remote fitting using in-situ testing.

Step 2: Prepare your patient

1. Schedule a phone/video call with the patient to provide instructions and confirm physical health of the outer ear and ear canal.
 - a. Ask the questions in the table below. If the answer is “yes” to any of the questions, refer the patient for medical evaluation prior to fitting the hearing aids.
 - b. In addition, the free CEDRA questionnaire can be used: <https://cedra.northwestern.edu/> Please note it is only available in English.
2. Confirm that the patient has a compatible iPhone or iPad.
3. Notify the patient that you will be sending the hearing aids.
 - a. Confirm that the patient is able to receive/pick up the hearing aids.
4. Notify the patient that you will be sending information by email:
 - a. Use the provided email template to obtain consent for GN Online Services. For full instructions on how to obtain consent, please see Appendix A: How to obtain consent for GN Online Services from your patient.
 - i For curbside pick-up, a printed copy of the consent form can be prepared for the patient to sign.

Does the patient exhibit or report:			
1	Visible congenital or traumatic deformity of either ear?	Y	N
2	Active drainage from ear(s) within the last 90 days?	Y	N
3	Sudden or rapidly progressive hearing loss, unilateral or bilateral, within the last 90 days?	Y	N
4	Acute or chronic dizziness?	Y	N
5	Sudden onset or increase in severity of tinnitus within the last 90 days?	Y	N
6	Pain in the ear(s)?	Y	N
7	Evidence of cerumen accumulation or foreign body in the ear canal(s)?	Y	N

- b. Use the provided email template to send instructions to the patient on how to download and install the app and how to get started with Live Assistance. **Ensure that the patient understands that this must be done before the Live Assistance call can be initiated.** You may choose to:
 - i. Attach the Get Connected Quick Guide.
 - ii. Attach the ReSound Assist Live Quick Guide.

¹ Existing patients are patients who have been fitted with a hearing aid before (this could be ReSound devices or other brands).

Step 3: Prepare the hearing aids

1. Ensure you are using the latest version of the ReSound Smart Fit fitting software.
2. Choose the appropriate device and power level for the patient based on the audiogram on file.
3. Verify the hearing aids meet ANSI specifications using a test box.
4. Open the patient's file in NOAH.
5. Connect the hearing aids to ReSound Smart Fit and advance to the Fitting screen.
 - a. Fit the hearing aids, based on the audiogram.
 - b. Login to GN Online Services (in the top right corner of the screen).
6. Verify that Remote Fine Tuning and Live Assistance are enabled.
 - a. Complete the consent process on behalf of the patient. For full instructions on how to obtain consent, please see Appendix A: How to obtain consent for GN Online Services from your patient.
 - b. It is not necessary to enter the patient's email address when prompted, as this will initiate an email containing the full consent document which the patient has already received and agreed to.
7. Save the settings in the hearing aids and exit ReSound Smart Fit.
8. Before packaging the hearing aids, ensure assembly of the devices. Attach any receivers/tubes and the selected domes or molds:

For RIE/thin tube BTE devices

- a. Attach receivers/thin tubes:
 - Determine receiver power by comparing the patient's hearing loss to the fitting ranges in ReSound Smart Fit.
 - For new patients: Choose a receiver wire/thin tube length of a medium size. If in doubt, choose a longer receiver wire/thin tube

length to avoid a too-tight fit over the ear. A receiver wire/thin tube length that is too short may cause discomfort and/or skin irritation. Receiver wire/thin tube length can be changed at the follow-up in-office appointment.

b. Attach domes:

- For new patients, or patients shifting to RIE/thin tube BTE devices: Choose tulip domes. Domes can be changed at the follow-up in-office appointment.
- For existing RIE/thin tube BTE patients: Choose same dome size as for current hearing aids. If in doubt, choose tulip domes or choose a smaller dome size to avoid undue pressure from a dome that is too large.
- For all patients: Include at least four extra domes. Different dome sizes/types can be included for the patient to exchange, with proper instruction.

For BTE (2mm tubes / #13 tubing) devices

- a. Attach tubing and molds.
 - b. Include extra tubing to ensure that the patient has an ample supply until the follow-up in-office appointment.
9. Mark the page in the patient guide that demonstrates insertion and removal of the devices, as well as care and maintenance of the devices. For RIE and thin tube BTE devices, also mark pages with dome attachment.
 10. Include the Get Connected Guide (can also be sent by email).
 11. Include the ReSound Assist Live Quick Guide (can also be sent by email).
 12. Depending on which model hearing aid is being fitted, verify that the devices are fully charged (if rechargeable) or include an ample supply of batteries.

13. Deliver the hearing aids to the patient. Notify the patient of the tracking number, if relevant and available.

Step 4: Live Assistance setup (Hearing Care Professional)

1. Verify web camera and microphone are working.
2. If real-ear equipment is used in the office, it must be completely disconnected from the PC before initiating Live Assistance.
3. Verify that a NOAHlink Wireless is connected to your PC.

Step 5: Check that the patient is ready to receive the Live Assistance call

Make a phone call to the patient to check that he/she is ready to receive the Live Assistance call:

- a. The ReSound Smart 3D app is downloaded and installed.
- b. The patient has connected the hearing aids in iOS settings.
- c. The patient has connected the hearing aids to the app.
- d. The patient has accepted the app's access to the iOS device's camera and microphone.
- e. It is important that the patient wear the hearing aids during the Live Assistance call as the sound will be routed directly to the hearing aids.
- f. Verify that the patient understands how to insert the hearing aids and that the fit is appropriate to make the Live Assistance call.

Step 6: Live Assistance call with the patient

1. Only the Hearing Care Professional can initiate a Live Assistance call.
 - a. Open the patient's file in NOAH and choose "Simulate" in the bottom right corner, then proceed to Fitting screen.

- b. Login to GN Online Services.
 - c. Select "Start Live Assistance" in the left navigation panel.

2. Make sure the patient can hear through Live Assistance.
3. Check that the physical fit of the hearing aids is appropriate.
 - a. For a new patient, or a patient shifting to a new style, be prepared with a set of similar devices to demonstrate through video how to place the hearing aids on the ears if needed.
 - b. Observe the patient through video to ensure that the hearing aids have been inserted with the power domes correct. Ask the patient to turn to the side to the phone/camera, so you can see their ears and the hearing aids.
 - c. For curbside pick-up, you can check the physical fit on the patient before leaving.
4. Connect the hearing aids.
5. Instruct the patient to remove the hearing aids if the sound is uncomfortable during the fitting.
6. Calibrate the feedback reduction system (DFS).
7. Make programming adjustments as in a normal session.
 - a. Adjusting the Tinnitus Sound Generator - for existing patients only:
 - i Tinnitus Sound Generator (TSG) cannot be activated for initial fittings via Live Assistance. Initial activation of TSG must take place at an in-office visit, however, transfer of TSG settings from a previous hearing aid is not considered an initial fit, as the patient has previously been fitted with TSG at an in-office visit.
 - ii. Live Assistance can be used to adjust the TSG for a patient who had it activated in an in-office fitting. For US only: This will be possible from June 2020.

8. Save the fitting and disconnect the hearing aids. This will apply the fitting to your patient's hearing aids.
9. Ample time should be spent coaching new patients, or patients who are shifting to a new hearing aid style, on proper insertion/removal of devices, correct assembly of dome and receiver, charging/changing batteries, cleaning, care and maintenance, and expectations for daily use.*
 - a. All the above steps can be demonstrated over the video call using the same devices and tools as in the clinic.
 - b. Again, use a similar set of devices to demonstrate on the call.
 - c. Also refer to the instructions described in the patient guide accompanying the hearing aids.
 - d. Patients should be encouraged to keep a daily journal to track their usage of the hearing aids and to document their experience with them.
10. Schedule a follow-up Live Assistance call within 48 hours of the fitting*.

Step 7: Follow-up meeting in the clinic

After a remote fitting (first fit), it is recommended to conduct a follow-up visit in the office at first opportunity (within 30 days).

- a. For new patients: at the follow-up visit, conduct a full hearing evaluation and make fine-tuning adjustments, including real-ear measurements (REMs), to the hearing aids
- b. For existing patients: At the follow-up visit, conduct a full audiogram along with REMs and fine-tuning adjustments.

* Treat the Live Assistance appointment exactly as the normal in-office fitting. All normal procedures conducted at these visits should be conducted through Live Assistance.

Additional guidance for remote fitting using in-situ testing

The following guidance is recommended when you perform a remote fitting of a new hearing aid using in-situ testing together with ReSound Assist Live (Live Assistance). The guidance is designed to ensure the fit's accuracy and the patient's safety.

The Live Assistance appointment should be treated exactly as a normal in-office hearing aid fitting. All normal procedures conducted at these visits should be conducted through Live Assistance.

Please note:

- This guidance assumes that national as well as other regulations and guidance for hearing aid fitting are followed, e.g., medical evaluation, reimbursement regulation, etc.
- For the US: Please ensure that you remain familiar with and in compliance with federal, state and local rules and regulations applicable to your practice as they relate to remote fitting. Regulatory requirements in this area of practice are constantly evolving, including with regard to remote medical evaluations and the practice of remote care across state lines.
- This guidance is relevant for new patients, where there is no audiogram available or for existing (1) patients, where only an outdated audiogram is available and in-situ testing is therefore used to fit the hearing aids.

1 Existing patients are patients who have been fitted with a hearing aid before (this could be ReSound devices or other brands).

Required software to enable Live Assistance:

- o Latest version of the ReSound Smart Fit fitting software.
- o Latest version of the ReSound Smart 3D app (v. 1.7.0 or newer)



WARNING: Instructions provided in this document for choice of hearing aid style must be followed.



WARNING: Tinnitus Sound Generator (TSG) cannot be activated for initial fittings via Live Assistance. Initial activation of TSG must take place at an in-office visit.



GENERAL WARNINGS:

- Prior to shipment to the user for remote fitting, hearing aids must be pre-programmed to older thresholds or 0 dB HL if thresholds are unknown.
- Correct insertion of hearing aids must be ensured before in-situ testing.
- Ample time must be given for the user to respond to tones during in-situ test.
- In-situ testing shall be done in a quiet place.



GENERAL WARNINGS:

- Domes can get detached and stuck in ear canal. If they are not removed in timely manner, it can cause damage to tissue in the ear canal.
- Open domes or too-small domes can lead to in-situ tones being played louder than intended. This can cause an incorrect test result and can lead to gain being set too high.
- A receiver wire that is too short can cause skin irritation on top of the outer ear.
- LP or MP receivers must be chosen for first-time users.

Overview of steps to take

1. Prepare your patient. Important: Consent for GN Online Services must be obtained.
2. Prepare the hearing aids: Fit and assemble the hearing aids before delivering to your patient.
3. Prepare your Live Assistance setup.
4. Check that the patient is ready to receive the Live Assistance call: The ReSound Smart 3D app must be downloaded and connected to the hearing aids.
5. Conduct the Live Assistance call with the patient.
6. Follow-up meeting in the clinic.

APPENDIX A: How to obtain consent for GN Online Services from your patient

Hearing aid styles for remote fitting using in-situ testing

Receiver-In-the-Ear (RIE)

- For new patients: Only LP, MP or MM
- For existing hearing aid patients only: LP, MP, HP, UP or MM

Behind-the-Ear (BTE) – for existing hearing aid patients only

- BTEs with standard 2mm tubing
 - o Please note: Patients currently wearing a BTE with thin tube must be fitted with a RIE device instead.

Super Power models are not supported.

Step 1: Prepare your patient

1. Schedule a phone/video call with the patient to provide instructions and confirm physical health of the outer ear and ear canal.
 - a. Ask the questions in the table below. If the answer is “yes” to any of the questions, refer the patient for medical evaluation prior to fitting the hearing aids. Log in to GN Online Services (in the top right corner of the screen)

Does the patient exhibit or report:			
1	Visible congenital or traumatic deformity of either ear?	Y	N
2	Active drainage from ear(s) within the last 90 days?	Y	N
3	Sudden or rapidly progressive hearing loss, unilateral or bilateral, within the last 90 days?	Y	N
4	Acute or chronic dizziness?	Y	N
5	Sudden onset or increase in severity of tinnitus within the last 90 days?	Y	N
6	Pain in the ear(s)?	Y	N
7	Evidence of cerumen accumulation or foreign body in the ear canal(s)?	Y	N

b. In addition, the free CEDRA questionnaire can be used:
<https://cedra.northwestern.edu/> Please note that it is only available in English.

2. Confirm that the patient has a compatible iPhone or iPad.
3. Confirm that the patient is able to receive/pick up the hearing aids.
4. Notify the patient that you will be sending the hearing aids.
 - a. For new patients: Inform the patient that the devices will be set up with no amplification until they are programmed during the Live Assistance call.
5. Notify the patient that you will be sending information by email:
 - a. Use the provided email template to obtain consent for GN Online Services. For full instructions on how to obtain consent, please see Appendix A: How to obtain consent for GN Online Services from your patient.
 - i. For curbside pick-up, a printed copy of the consent form can be prepared for the patient to sign.
 - b. Use the provided email template to send instructions to the patient on how to download and install the ReSound Smart 3D app and how to get started with Live Assistance. **Ensure that the patient understands that this must be done before the Live Assistance call can be initiated.**

You may choose to:

- ii. Attach the Get Connected Quick Guide.
- iii. Attach the ReSound Assist Live Quick Guide.

Step 2: Prepare the hearing aids

1. Ensure you are using the latest version of the ReSound Smart Fit fitting software.
2. Choose appropriate device and power level for the patient:
 - a. For new patients: Choose an RIE device with either LP or MP receiver.
 - b. For existing patients: Choose one of the devices listed above under “Product range” and “Hearing aid styles” based on the audiogram on file.
3. Verify the hearing aids meet ANSI specifications using a test box.
 - a. This is an important step in order to secure an accurate in-situ test result for the programming of the hearing aids.
4. Open the patient’s file in NOAH.
 - a. For new patients: Create a new file and enter the audiogram as 0 dB at 250 Hz and 4000 Hz for both ears in the NOAH Audiogram Module or in Standalone ReSound Smart Fit.
 - b. For existing patients: No changes to the audiogram on file need to be made.
5. Set the experience level:
 - a. For new patients: Choose a conservative experience level, either First Time Patient or Comfort Patient.
6. Connect the hearing aids to ReSound Smart Fit and advance to the Fitting screen.
 - a. Fit the hearing aids:
 - For existing patients: Use the audiogram and other patient information on file as the basis of the first fitting.
 - b. Log in to GN Online Services (in the top right corner of the screen).
7. Verify that Remote Fine Tuning and Live Assistance are enabled.
 - a. Complete the consent process on behalf of the patient. For full instructions on how to obtain consent, please see Appendix A: How to obtain consent for GN Online Services from your patient.
 - b. It is not necessary to enter the patient’s email address when prompted, as this will initiate an email containing the full consent document that the patient has already received and agreed to.
8. Save the settings in the hearing aids and exit ReSound Smart Fit.
9. Before packaging the hearing aids, ensure assembly of the devices to be ready for in-situ testing.

For RIE devices

- a. Attach receivers:
 - For new patients: Choose an LP or MP receiver with a wire length of a medium size. If in doubt, choose a longer receiver length to avoid a too-tight fit over the ear. A receiver length that is too short may cause discomfort and/or skin irritation. Receiver length can be changed at the follow-up in-office appointment.
- b. Attach domes for in-situ testing:
 - Power domes must be attached to ensure accuracy of in-situ testing. Select a dome size that will occlude the ear during in-situ testing. If a large power dome is attached to the hearing aids, also include medium size power domes to avoid the domes not being able to fit in the ear canal.
 - Note that a non-occluding dome fit can lead to venting (i.e., in-situ tones being played louder) and result in an incorrect in-situ result, which can lead to gain being set too high.

c. Provide domes for everyday wear after in-situ testing:

- For new patients or patients shifting to RIE devices: Choose tulip domes. Domes can be changed at the follow-up in-office appointment.
- For existing RIE patients: Choose same dome size as for current hearing aids. If in doubt, choose tulip domes or choose a smaller dome size to avoid undue pressure from a dome that is too large.
- For all patients: Include at least four extra domes. Different dome sizes/types can be included for the patient to change, with proper instruction.

For BTE devices (2mm tubes / #13 tubing) – for existing patients only

a. Set up for in-situ testing:

- In-situ testing can be performed as a quick check with the patient's own mold and the standard 2 mm tube. Please note that if the vent in the mold is larger than a pressure vent/comfort vent, the in-situ test result will not be as accurate below 1 kHz as it would with a more closed solution.

b. For everyday wear, include extra tubing to ensure that the patient has ample supply until the follow-up in-office appointment.

10. Mark the page in the patient guide that demonstrates insertion and removal of the devices, as well as their care and maintenance. For RIE devices, also mark pages with dome attachment.
11. Include the Get Connected Guide (can also be sent by email).
12. Include the ReSound Assist Live Quick Guide (can also be sent by email).
13. Depending on which model hearing aid is being fitted, verify that the devices are fully charged (if rechargeable) or include an ample supply of batteries.
14. Deliver the hearing aids to the patient. Notify the patient of the tracking number, if relevant and available.

Step 3: Live Assistance setup (Hearing Care Professional)

1. Verify web camera and microphone are working.
2. If real-ear equipment is used in the office, it must be completely disconnected from the PC before initiating Live Assistance.
3. Verify that a NOAH link Wireless is connected to your PC.

Step 4: Check that the patient is ready to receive the Live Assistance call

1. Make a phone call to the patient to check that he/she is ready to receive the Live Assistance call:
 - a. The ReSound Smart 3D app is downloaded and installed.
 - b. The patient has connected the hearing aids in iOS settings.
 - c. The patient has connected the hearing aids to the app.
 - d. The patient has accepted access for the app to the iOS device's camera and microphone.
 - e. It is important that the patient wear the hearing aids during the Live Assistance call as the sound will be routed directly to the hearing aids.
 - For new patients: Inform the patient that the hearing aids will be muted until connected at the Live Assistance call and that the volume might need to be adjusted in the beginning of the call.
 - f. Verify that the patient understands how to insert the hearing aids and that the fit is appropriate to make the Live Assistance call.

Step 5: Live Assistance call with the patient

1. Only the Hearing Care Professional can initiate a Live Assistance call.
 - a. Open the patient's file in NOAH and choose "Simulate" in the bottom right corner, then proceed to Fitting screen.
 - b. Login to GN Online Services.
 - c. Select "Start Live Assistance" in the left navigation panel.
2. Make sure the patient can hear through Live Assistance.
 - a. For new patients it might be necessary to increase the gain from the 0dB gain setting.
3. Check that the physical fit of the hearing aids is appropriate before the in-situ testing.
 - a. For a new patient, be prepared with a set of similar devices to demonstrate through video how to place the hearing aids on the ears if needed.
 - b. Observe the patient through video to ensure that the hearing aids have been inserted with the power domes correct. Ask the patient to turn to the side to the phone/camera, so you can see their ears and the hearing aids.
 - c. For curbside pick-up, you can check the physical fit on the patient before leaving.
4. Instruct the patient to be in a quiet place for the in-situ testing.
5. Connect the hearing aids and conduct in-situ testing.
 - a. Instruct the patient on in-situ testing: Explain how the patient should respond to the in-situ signals when heard (e.g., hand raise, verbal response – choose most appropriate).
 - b. If the internet connection is not robust, there may be a delay between initiating the signal via in-situ and when the patient hears it; click slowly to present the tones. Allow adequate time for the patient to respond.
 - c. For existing patients with an audiogram on file: Use in-situ as a quick check to ensure that the hearing has not changed before proceeding to fit.
6. Save in-situ test results and choose "Apply to fitting".
7. Before moving on to the fitting, verify that the fitting range of the chosen device and dome/mold are appropriate for the patient.
8. Once in-situ testing is complete, the patient will need to remove the power domes and attach the domes provided in the package.
 - a. Refer the patient to the marked page in the patient guide for how to change the domes and demonstrate over the video call with similar devices so that patient can see it done in real time before making the change.
9. Instruct the patient to remove the hearing aids if the sound is uncomfortable during the fitting.
10. Calibrate the feedback reduction system (DFS).
11. Make programming adjustments as in a normal session.
 - a. For new patients: Ensure a conservative experience level has been selected, either First Time Patient or Comfort Patient.
 - b. Adjusting the Tinnitus Sound Generator - for existing patients only:
 - i. Tinnitus Sound Generator (TSG) cannot be activated for initial fittings via Live Assistance. Initial activation of TSG must take place at an in-office visit, however, transfer of TSG settings from a previous hearing aid is not considered an initial fit, as the patient has previously been fitted with TSG at an in-office visit.

- ii. Live Assistance can be used to adjust the TSG for a patient who had it activated in an in-office fitting.
- 12. Save the fitting and disconnect the hearing aids. This will apply the fitting to your patient's hearing aids.
- 13. For new patients or patients who are shifting to a new hearing aid style, ample time should be spent coaching them on proper insertion/removal of devices, correct assembly of dome and receiver, charging/changing batteries, cleaning, care and maintenance, and expectations for daily use.*
 - a. All the above steps can be demonstrated over the video call using the same devices and tools as in the clinic.
 - b. Again, use a similar set of devices to demonstrate on the call.
 - c. Also refer to the instructions described in the patient guide accompanying the hearing aids.
 - d. Patients should be encouraged to keep a daily journal to track their hearing aid usage and document their experience with the hearing aids.
- 14. Schedule a follow-up Live Assistance call within 48 hours of the fitting*.

*Treat the Live Assistance appointment exactly as the normal in-office fitting. All normal procedures conducted at these visits should be conducted through Live Assistance.

Step 6: Follow-up meeting in the clinic

After a remote fitting (first fit), it is recommended to conduct a follow-up visit in the office at first opportunity (within 30 days).

- a. For new patients: at the follow-up visit, conduct a full hearing evaluation and make fine-tuning adjustments, including real-ear measurements (REMs), to the hearing aids.
- b. For existing patients: At the follow-up visit, conduct a full audiogram along with REMs and fine-tuning adjustments.

APPENDIX A

How to obtain consent for GN Online Services from your patients

Follow these steps:

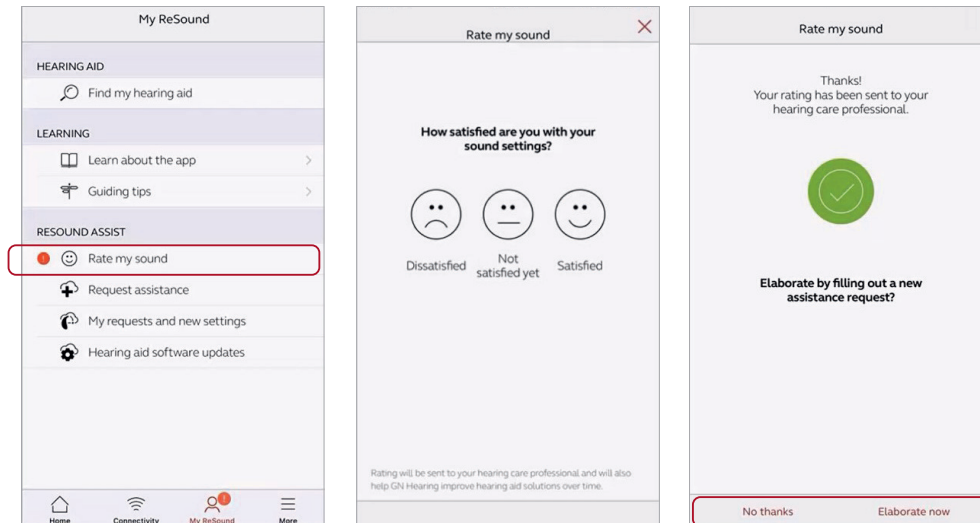
1. Preparation for the Hearing Care Professional:
 - a. Fill in your name and contact details in the email template where highlighted in yellow before sending to your patients.
 - b. Fill in your name and contact details in the consent document “Consent for GN Online Services” where highlighted.
2. Obtaining the consent:
 - a. We recommend that you inform your patient about the need for consent to GN Online Services in a phone call prior to sending the email so they are prepared.
 - b. Send email with attached full consent document to your patient.
 - c. For curbside pick-up, a printed copy of the consent form can be prepared for the patient to sign.
 - d. Receive consent back from patient.
 - e. Keep record of consent as per standard procedure.
3. When fitting the hearing aids for your patient:
 - a. In ReSound Smart Fit, enter Accept to the consents on behalf of and as agreed by the p (“Agree A” or “Agree A and B”).
 - b. Enable Remote Fine Tuning and Live Assistance.
4. If your patient replies with “Do not agree”:
 - a. Remote Fine Tuning and Live Assistance cannot be enabled for the patient, and the remote fitting flow cannot continue.

Rate My Sound

Communication with patients shouldn't stop after a fine-tuning. The new fitting performance rating system, Rate My Sound, allows them to give you real-world feedback about how they are adjusting to the new settings and if they need any follow-up fine-tunings. Hearing from them while they are in the listening situations they find most difficult gives you the most accurate information you need to provide the best care. And you'll get their input, regardless of whether the fine-tuning was in-office or via ReSound Assist.

Rating settings from the HCP

1. The patient will be prompted to rate the fitting three days after an in-office fitting or after installing fine-tuned settings, to the hearing aid, via ReSound Assist. The prompt will appear as a push notification from the phone and there will be a badge on the "My ReSound" icon within the ReSound Smart 3D app.
2. Click to either rate the settings immediately, postpone to be notified again in the future, or choose not to rate the settings.
3. To rate, on the "My ReSound" screen tap "Rate my sound" and tap the appropriate satisfaction level.
4. If the rating is based on a follow-up fitting, there will be an opportunity to also give feedback on whether the settings are better or worse than the previous settings.
5. If "Not satisfied yet" or "Dissatisfied" is selected, the patient is encouraged to send a new service request, along with the rating, in an attempt to troubleshoot the complaint once again. To generate a new service request to be delivered to the HCP along with the rating, tap "Elaborate now" and follow the steps in "Assistance request is defined further" in this document.



Viewing patient ratings

1. Once a fitting or fine-tuned settings have been rated by the patient, an email notification will be received. If you would like to deactivate email notifications, go to the Patient section of GN Online Services.
2. The rating can be viewed within the ReSound Assist timeline. When a new assistance request has been sent along with the Rate My Sound rating, the new request will appear as the latest action in the timeline and the rating will be found below it.
3. If the HCP would like to generate a new set of fine-tuned settings at this time, follow the steps in “Starting an Assist fine-tuning session from the timeline” section of this document.

The screenshot displays the ReSound Assist timeline interface. On the left, a red notification bubble indicates a date of 20 Feb 2018. The main timeline area is titled "In-Office Session - 11:57 AM" and shows a "Rating: Not satisfied yet". Below the title, a table lists actions:

Action	Action by	Date	Time
Rate my sound Not satisfied yet	J. Snow	2/20/2018	11:57 AM Actions
In-Office Session Saved in cloud	C. Chan	2/13/2018	11:35 AM Actions

Below the table, the "Rating information from patient" section asks "How satisfied are you with your sound settings?". It features three smiley face icons: a sad face labeled "Dissatisfied", a neutral face labeled "Not satisfied yet", and a happy face labeled "Satisfied".

Tinnitus Sound Generator

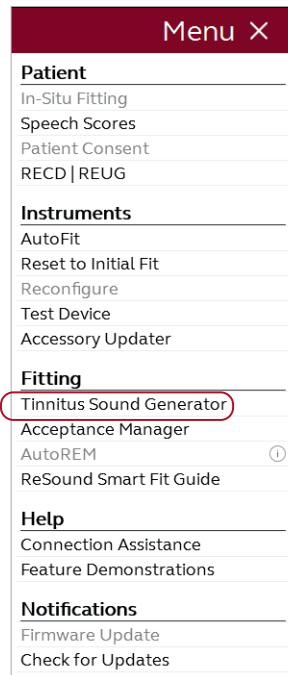
This guide assumes a fitting with a multi-program wireless hearing aid with ear-to-ear capability. Tinnitus patients have great variance in their needs and preferences for successful tinnitus management. The information in this fitting guide is designed to serve as suggested starting points, and can be modified as needed for individual patients.

Intended Use/Indications for Use of TSG

The TSG Module is a tool to generate sounds to be used in a tinnitus management program to temporarily relieve patients suffering from tinnitus. The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older. The Module is targeted for healthcare professionals treating patients suffering from tinnitus, as well as conventional hearing disorders. The Module fitting must be done by a hearing professional participating in a tinnitus management program.

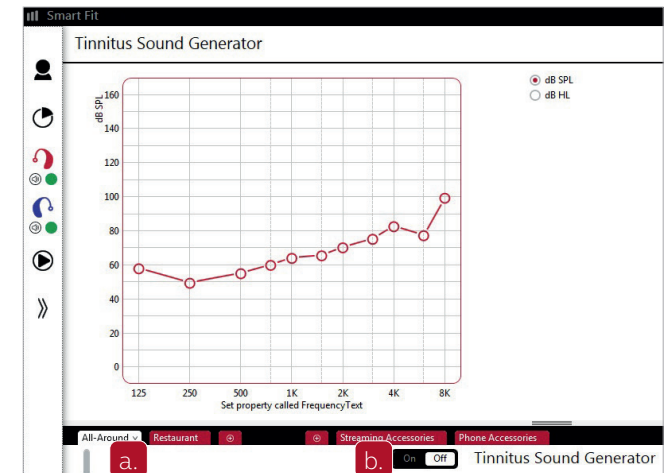
TSG target population

The target population is primarily those over 18 years of age. But it also can be used with children down to 12 years old. However, children and physically or mentally challenged patients will require training by a doctor, audiologist, hearing care professional or guardian for the insertion and removal of hearing aids.



Default programs

- P1 - All Around
Note: Directionality settings are All Access
Directionality for binaural fittings, SoftSwitching for monaural fittings; directionality settings are different for technology levels 5 and 7.
- P2 - Restaurant



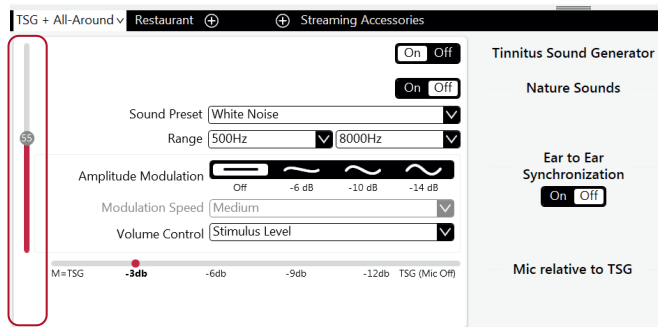
Select “Tinnitus Sound Generator” from “Menu” to start activating and fine tuning TSG.

1. TSG Activation:

- Select the program you need to combine with TSG from program tabs.
- Click “On” option to activate the TSG in combination with the selected program.

NOTES:

- The Tinnitus Sound Generator (TSG) features are the same in all technology levels, and can be activated in any program.
- The TSG volume slider is in dB SPL. The TSG settings and audiogram can be displayed in dB SPL or dB HL.
- The binaural link option is not available in the TSG setup, therefore programming changes need to be applied to the right and left sides separately, unless synchronization is active (see Step 4 on page 12).
- Mic settings relative to TSG balance, synchronization and volume control impact both Standard TSG and Nature Sounds.
- Please find the information about how long TSG may be used, in the General Warnings section.



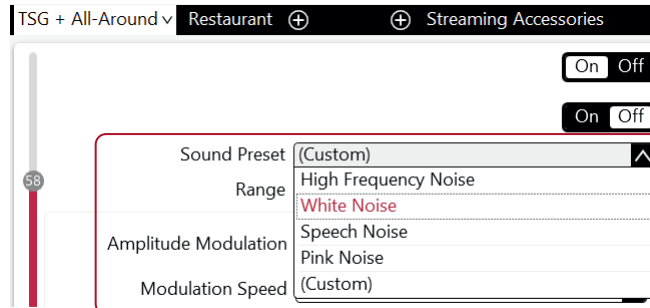
2. TSG volume

Set the TSG volume with the slider. The volume should be set to a level that provides relief, but does not completely mask the tinnitus. To prevent unintended signal increase by pediatric or physically or mentally challenged patients, the volume control must be configured to only provide a decrease of the sound generator output level. To do so, configure the “High Range Volume” to “0”, in the Manual Controls screen (ref. p. 10).

Below is a suggestion on how to first fit the TSG, using the audibility threshold as a starting point.

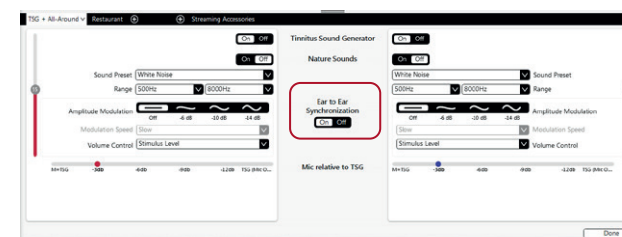
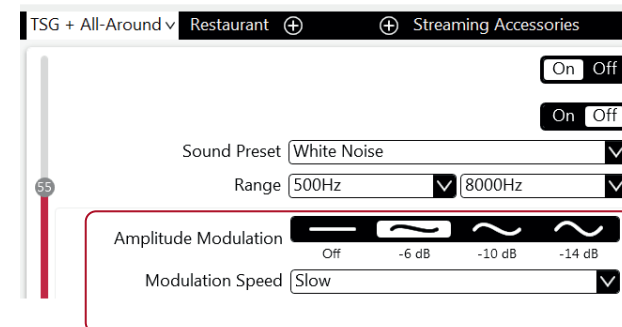
Find the TSG audibility threshold (three steps)

- Using the volume slider, turn up the volume until the patient reports that they can just barely hear the TSG white noise. This is the TSG audibility threshold.
- Increase the volume slider until the patient reports no longer hearing the tinnitus over the TSG sound. This is the level at which the tinnitus is completely masked. This is the minimum masking level (MML).
- Set the volume 5–10 dB above the threshold level. Note: You can go higher than 10 dB if necessary, but do not completely mask the tinnitus signal. This is where the MML is important.



3. Set the TSG bandwidth

Our TSG defaults to a broadband white noise setting. There are four sound preset options to choose from. They can be customized using the range option to adjust the frequency shaping. Note: Any change in the volume or frequency shaping setting will default the sound preset to a “Custom” label.



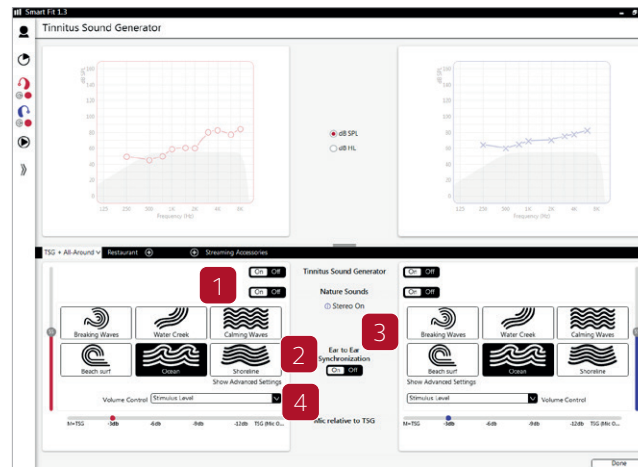
4. Customize the TSG features according to patient's preference

- “Amplitude Modulation” can be activated if the patient finds it to be comfortable.
- “Amplitude Modulation” causes the TSG to fluctuate in volume, creating an “ocean-like” noise sequence. A “Mild” setting offers less fluctuation, whereas a “Strong” setting offers more fluctuation.
- “Modulation Speed” controls how quickly the volume fluctuations occur a “Slow” setting allows more time between fluctuations, whereas a “Fast” setting allows less time.
- Turn Synchronization “On” to enable ear-to-ear communication. Then any change to TSG features in one hearing aid automatically repeats in the other.



5. Customize the Volume Control options

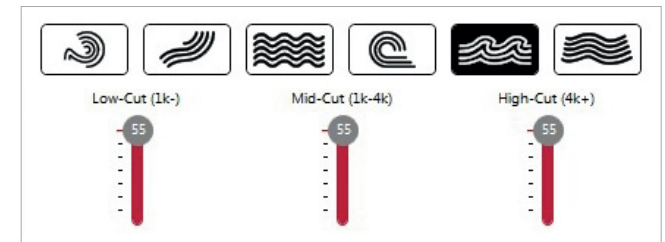
- The “Stimulus Level” options determine how the volume of the TSG will be controlled.
- Selecting “Stimulus Level” will reassign the function of the manual volume control to the TSG only for that program.
- Selecting “Stimulus Level + Environment” will combine the use of these two features. It will also allow manual volume adjustments while the Environment features are active.



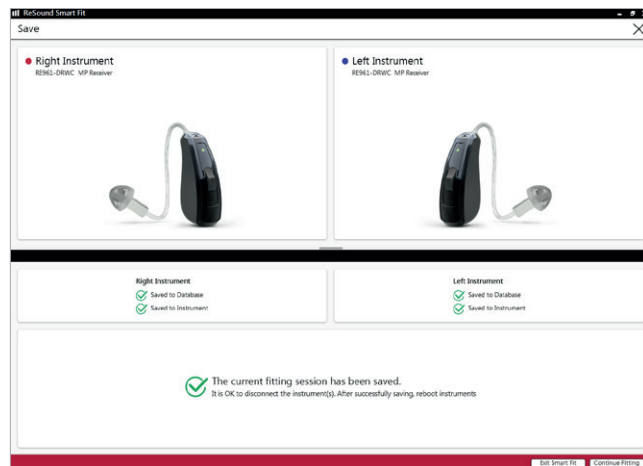
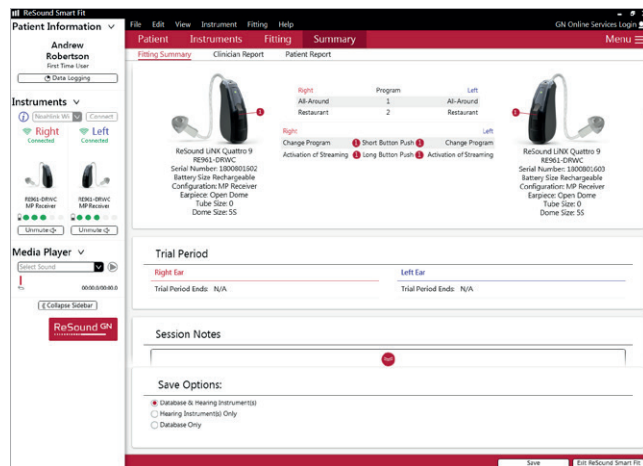
6. Activating Nature Sounds

Nature Sounds can be used as an alternative to the standard TSG.

1. Turn Nature Sounds “On”.
2. Activate the desired nature sound from six water-inspired options by clicking on their image. If “Synchronization” is “On” the selected sound will be automatically copied to the other side.
3. The stereo effect is “On” only when both hearing aids have similar Nature Sounds.
4. “Show Advanced Settings” displays options available for adjustment. Turn Nature Sounds “On”.



1. “Advanced Settings” allows you to adjust the low, mid and high frequency bands of the Nature Sounds. Note: It is only recommended to use Advanced Settings based on the patient’s needs.



7. Program and save

To program the hearing aids and save to Noah, click “Save” in lower part of “Fitting” screen or “Summary” screen.

Using the Tinnitus Sound Generator with the ReSound Smart 3D™ app

This section provides guidance on the functions available to your patients in the ReSound Smart 3D app.

When you enable TSG in your patient's ReSound hearing aids during a fitting, your patient gets access to the Tinnitus Manager in the app. A small tinnitus icon will show in the top right corner of the program button(s) in the app where TSG has been fitted and the Tinnitus Manager will appear in the "Sound Enhancer" menu for each TSG-fitted program.

Any adjustments made with the Tinnitus Manager are made per program, and in the same discrete steps as are available in the fitting software. Adjustments can be saved as "Favorites" in the app but are not saved in the hearing aids. Tinnitus Manager is only available in supported hearing aids.

To return to the program fitted settings, tap "Reset".

What your patient has access to in the ReSound Smart 3D app

The TSG volume level, frequency shaping, white noise variation and Nature Sound can be adjusted by the patient, but the adjustments will be deleted upon closing the Smart 3D app, unless they are saved as a Favorite, which can later be accessed manually when reopening the Smart 3D app.

The TSG volume can only be adjusted within the range set by the hearing care professional.

When closing the Smart 3D app, any adjustments will be deleted and default back to the settings made by the hearing care professional.

When fit with white noise

Sound variation:

Activate or adjust the white noise signal by tapping one of the four buttons in "White noise variations"

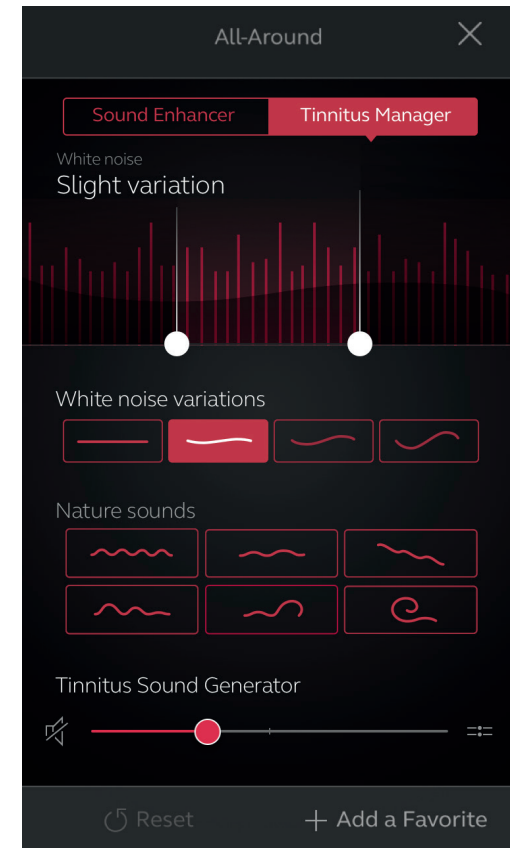
Levels of adjustment: Off, Slight, Moderate, Strong.

Adjust the *frequency shaping* by moving the two sliders left and right.

Levels of adjustment:

Low: Off, 500 Hz, 750 Hz, 1000 Hz, 1500 Hz, 2000 Hz

High: 2000 Hz, 3000 Hz, 4000 Hz, 5000 Hz, 6000 Hz, 8000 Hz, Off

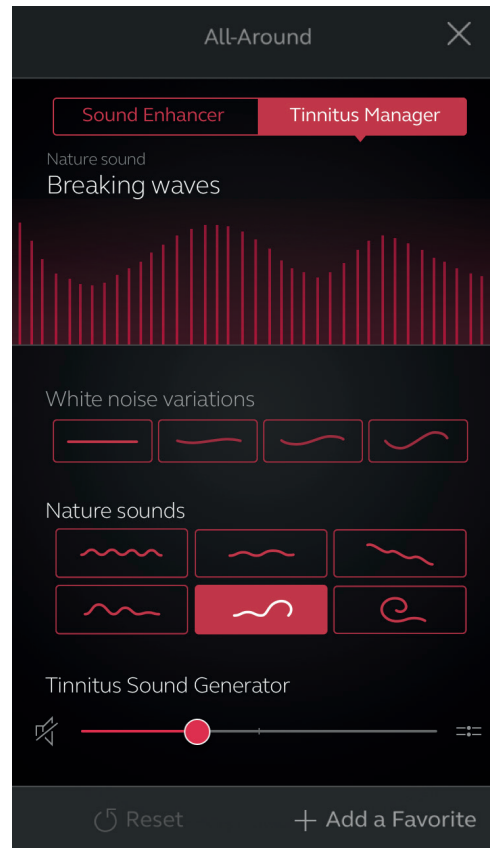


When fit with a Nature Sound

Activate or choose your preferred nature sound by tapping one of the six buttons in “*Nature sounds*”.

Volume Control

Adjust the *TSG* volume level by moving the slider.



Precautions and Warnings

General information for Hearing Care Professionals

- Hearing aids manufactured by GN ReSound A/S are compatible to and can be connected to receiver tubes manufactured by GN Hearing A/S.
- Only use original receiver tubes and domes for hearing aids manufactured by GN ReSound A/S.
- Make sure to hand over to the end patient only specified parts selected during fitting.
- The CE mark applies to the hearing aid only when the receiver tube is mounted on the hearing aid.

General Precautions

- This fitting software, Resound Smart Fit, must be installed and used by hearing care professionals only.
- The ReSound Smart Fit fitting software will apply recommended amplification settings based on available audiometrical information. Settings will be specific to each fitting.
- Manual modification of the fitting parameters will impact and change the prescribed amplification level. This change will be audible to the patient when the aids are connected.
- Caution should be exercised with patients sensitive to sounds, for example suffering from tinnitus or hyperacusis.
- Hearing device performance may drift and decline over time. Please ensure devices are performing within specifications prior to performing in situ threshold testing.
- Feature accuracy is reliant on the ear canal being completely occluded.

Security Awareness when using PC

- Lock your computer screen whenever you leave your computer (press Windows+L).
- Your password is personal and must never be shared or re-used with other sites or services.
- Anti-malware software should always be enabled.
- Always be on latest Windows Service Packs/Updates.
- Always have a healthy skepticism about external emails.

Pay special attention to seemingly sincere emails that try to trick you into giving away personal or confidential information such as your patient ID and passwords, or that try to make you take unwanted actions - such as clicking on an attachment or a link. The concept is called “phishing”.

Tinnitus Sound Generator

Caution should be exercised with patients sensitive to sounds, for example suffering from tinnitus or hyperacusis.

General Warnings

- When connected, the ReSound Smart Fit fitting software controls the acoustic amplification levels in a hearing aid. In some acoustic environments, overamplification may cause discomfort and damage to the patient’s hearing.
- The Fitting System provides initial default amplification settings based on hearing threshold levels. These default settings could be higher than stable levels and cause feedback when amplification is first applied.
- The Fitting System initiated the feedback calibration procedure. Feedback calibration uses broadband noise to measure the amount of sound leaking from the hearing aid. The output level is designed to be on the border of “uncomfortable” level based on the hearing threshold level at a specific frequency.

The sound will be ramped up in volume and cease when the calibration data is received. It is possible for the level to exceed a patient’s comfort level, but it needs to be determined if it can reach hazardous risk levels.

- The Fitting System initiates feedback calibration to measure the receiver-to-microphone transfer function. This is used primarily by the hearing aid to manage feedback suppression but it is also used to display the limits of stable gain.
- The maximum stable gain estimates are based on feedback calibration data, the presence of active feedback suppression, and a headroom estimate. The headroom value is meant to be conservative; however, the presence of directionality has been shown to give inaccurate estimates of maximum stable gain. The risk is that, under some situations, the Fitting System could show that the hearing aid is stable when it is actually close to unstable and in risk of feedback.
- If feedback calibration has not been performed during fitting, the Max Stable Gain is not known and the device could cause feedback without warning.
- The Fitting System uses the Audiogram+ algorithm to interpret audiogram data for determining optimal gain settings. The parameter used is “first time patient”. This may give a less than optimal initial fitting but should not pose a safety risk. The algorithm has been independently validated with the specification and verified to be consistent with the fitting software.
- The Fitting System uses feedback calibration measurements to compute maximum stable gain values. These values are an estimate of the amount of gain that can be safely applied to a hearing aid before it begins to cause feedback. There is a warning when this gain is reached, and the over-gain values are highlighted with bold red text. The safety margins give a close approximation of the actual feedback border. However, it is an estimation and feedback can occur before the warning is given. Sustained feedback on high power devices can damage residual hearing.

- Warning to hearing care professionals: Special care should be exercised in selecting and fitting hearing aids whose maximum sound pressure level exceeds 132 dB SPL with an IEC 60711: 1981 occluded ear simulator, because there may be a risk of impairing the remaining hearing of the hearing aid patient. Special care should be exercised in selecting and fitting a power hearing aid with a maximum sound pressure level that can exceed 132 dB SPL, as there may be a risk of further impairing the remaining hearing.
- Warning to hearing care professionals: Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level that exceeds 132 dB SPL, measured in a 2 cc acoustic coupler in accordance with IEC 60318-5:2006. The remaining hearing may risk further impairment.
- Warning to hearing care professionals: Special care should be exercised in selecting and fitting hearing aids utilizing Tinnitus Sound Generator. The maximum TSG output falls into the range that can cause hearing loss according to OSHA regulations. For further details please consult the patient guide of the relevant hearing aid that includes the Tinnitus Sound Generator feature. In compliance with NIOSH recommendations, the patient should not use the sound generator for more than eight (8) hours a day when it is set to a level of 85db SPL or above. When the sound generator is set to levels of 90db SPL or above the patient should not use it for more than two (2) hours per day. In no case should the sound generator be worn at uncomfortable levels.
- Children and physically or mentally challenged patients will require guardian supervision while wearing the device.

- If a hearing aid earpiece is changed, care must be taken to ensure that the perceived loudness and sound pressure level of TSG does not change when going from a more open earpiece to a more closed earpiece. An increased sound pressure level may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

Tinnitus Sound Generator

Warning to hearing healthcare professionals: Special care should be exercised in selecting and fitting hearing aids utilizing Tinnitus Sound Generator. The maximum TSG output falls into the range that can cause hearing loss according to OSHA regulations. For further details please consult the patient guide of the relevant Hearing Aid that includes the Tinnitus Sound Generator feature. In compliance with NIOSH recommendations, the patient should not use the sound generator for more than eight (8) hours a day when it is set to a level of 85db SPL or above. When the sound generator is set to levels of 90db SPL or above the patient should not use it for more than two (2) hours per day. In no case should the sound generator be worn at uncomfortable levels. Children and physically or mentally challenged patients will require guardian supervision while wearing the device.

A hearing healthcare professional should advise a prospective sound generator patient to consult promptly with a licensed physician (preferably an ear specialist) before getting a sound generator if the hearing healthcare professional determines through inquiry, actual observation, or review of any other available information concerning the prospective patient that the prospective patient has any of the following conditions:

1. Visible congenital or traumatic deformity of the ear.
 2. History of active drainage from the ear within the previous 90 days.
 3. History of sudden or rapidly progressive hearing loss within the previous 90 days.
 4. Acute or chronic dizziness.
 5. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
 6. An audiometric air-bone gap equal to or greater than 15dB at 500 hertz (Hz), 1000 Hz, and 2000 Hz.
 7. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
 8. Pain or discomfort in the ear.
- To prevent unintended usage by pediatric or physically or mentally challenged patients, the volume control must be configured to only provide a decrease of the sound generator output level.
 - Adjustment of the Tinnitus Sound Generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the patient is a minor.
 - Use of the ReSound Assist feature for remote settings of the Tinnitus Sound Generator should only be performed by the parent or legal guardian in cases where the patient is a minor.

Manufacturer according to FDA:

GN ReSound North America
8001 E Bloomington Freeway
Bloomington, MN 55420
USA
1-800-248-4327
resoundpro.com

ReSound Government Services
8001 E Bloomington Freeway
Bloomington, MN 55420
USA
1-800-392-9932
resound.com/veterans

Manufacturer according to Health Canada:

ReSound Canada
2 East Beaver Creek Road, Building 3
Richmond Hill, ON L4B 2N3
Canada
1-888-737-6863
resoundpro.com