

Fitting software

Beltone Solus Max™

User guide

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! Before using your hearing aids and associated devices, ensure that you read "General warnings and cautions", page 38. You should also pay close attention to warnings embedded throughout this user guide.

Introduction

This user guide is valid for Beltone Solus Max version 2.4.

Beltone Solus Max is fitting software used for Beltone Trust and newer hearing aids.

NOTE: Read this booklet carefully before using the fitting software for the first time.

Software updates

Beltone A/S will support each release of fitting software for a maximum 6 months (expected service life time). If during this period any security vulnerabilities are identified, Beltone A/S will issue an update to this fitting software release (e.g. a patch).

Once a fitting software release is older than 6 months, you must update to a newer supported version to ensure the system remains secure to use from a cybersecurity perspective. Beltone A/S cannot guarantee that a fitting software release older than 6 months to be secure from a cybersecurity perspective.

For information about any software components that are included in this product (software bill of materials), contact Beltone A/S support.

Intended purpose

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

User profile

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

Therapeutic indications

The accessory has no therapeutic indications in itself.

Contraindications

No known contraindications.

General information

- Hearing aids manufactured by Beltone A/S are compatible to and can be connected to receivers manufactured by GN Hearing A/S.
- Only use original receivers and domes manufactured by GN Hearing A/S.
- Ensure that the patient is only provided with the exact parts that were selected during the fitting process.

Cybersecurity

Hearing aid system

The following diagram illustrates the communication interfaces of the hearing aid system. The hearing aid system consists of several devices, such as the hearing aids, charger[1], app, fitting software, microphone, and TV streamer.

The diagram shows how these devices communicate with each other, how data is stored in the cloud, and how a TV streamer connects to the television. It also shows that the TV streamer and external microphone can be used for Auracast broadcasts.

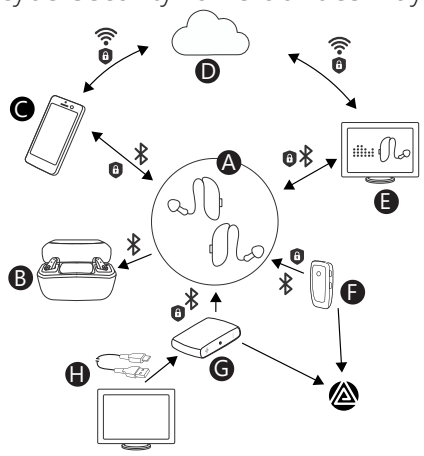
If a device is not described in detail in this user guide, it is described in it its own user guide.

Communication only takes place if you consent and if the hearing aids are paired with a mobile device.

To ensure data security and patient confidentiality, the hearing aid system employs standard cybersecurity measures built into the protocols, along with additional security features such as authentication, data encryption, data integrity protection, and data validation.

[1] Chargers are only available for rechargeable hearing aids. If your hearing aids use replaceable zinc-air batteries, a charger is not part of your hearing aid system.

NOTE: If you use the software components beyond their intended service life, the risk of cybersecurity vulnerabilities may increase over time



A. Hearing aids
B. Charger
C. Mobile device
D. Cloud
E. Fitting software
F. External microphone
G. TV streamer
H. TV

Communication between the various devices is undertaken by one of the following:

- Bluetooth®
- Wireless
- Cable
- Auracast

The diagram illustrates whether the connection is encrypted.

The following table explains the data exchange between the various devices referenced in the diagram.

Connection from	Connection to	Exchanged data
Hearing aids	Charger	• Current battery level • Verifies whether a proper hearing aid is inserted into in the charger
	Mobile device	• Current settings, including volume and listening environments
	Fitting software	• Current settings
Mobile device	Hearing aids	• New settings • Firmware updates
	Cloud	• Current settings • End user registration • Requests for remote fine tuning (if applicable)

Connection from	Connection to	Exchanged data
Cloud	Mobile device	• Latest settings • Firmware updates • Remote fine tuning (if applicable)
	Fitting software	• Firmware update • Requests for remote fine tuning (if applicable)
Fitting software	Hearing aids	• New fitting settings • Firmware updates
	Cloud	• Current settings • Remote fine tuning (if applicable)
TV streamer	Hearing aids	• Encoded audio
	Auracast	• Encoded audio
External microphone	Hearing aids	• Encoded audio
	Auracast	• Encoded audio

⚠ Warnings and cautions

- Contact Beltone support if your fitting software is malfunctioning.
- If the hearing aids consistently fail to connect to or continuously disconnect from the fitting software, contact Beltone support.
- All stored patient data in fitting software is encrypted, and GN Online Services require credentials authentication to access patient data.
- All wireless communication in the Beltone system are encrypted and authenticated to protect your data and prevent unauthorized access to the system.
- The software is secured with code signing to guarantee that it has not been altered or compromised.
- Uninstall and reinstall the fitting software if you suspect that it has been compromised.
- The device comes signed and with certificates, and no further configuration is required.
- The cloud services store access attempts, crashes, erroneous usage, and firmware downloads and updates.
- If you stop using the fitting software, you should delete it from your computer. Note that data in the separate patient and session database is not deleted. Consider whether this data should be retained or deleted.

How to start

This section lists system requirements and explains how to install and get started using the fitting software.

The fitting software should only be installed and used by hearing care professionals. It is recommended to always update the fitting software to the latest version available.

For additional support materials please visit www.beltone.com/en/support.

System requirements

Before installing the fitting software, ensure that you are all set with your computer and programming interfaces.

For wired programming, a connector system is needed to connect to the hearing aids. These connector systems can be purchased through your supplier.

The descriptions for the different connector systems:

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

SUPPORTED OPERATING SYSTEMS
• Windows 10 – 32 & 64-bit – All service packs
• Windows 11 – 64-bit
Windows 7, Windows 8 and Windows 8.1 and earlier versions are not supported.
SUPPORTED PATIENT DATABASE
• Noah 4
SUPPORTED PROGRAMMING INTERFACES
• Noahlink Wireless
• Noahlink
• Speedlink
• Hi-PRO 2

SUPPORTED REM MODULES	
MANUFACTURER	MODULE NAME
Auditdata	Primus & Measure
Interacoustics	Affinity Compact, Affinity Suite, Callisto Suite
Inventis	Trumpet
MedRx	Avant
Natus Medical	Free Fit
Sivantos	Unity 3
Amplifon	OtoPad

Manufacturer and module compatibility is subject to change. Contact customer support for the latest information.

SYSTEM REQUIREMENTS	
Processor	Intel Core i5 or similar
RAM	8 GB
Free HD	10 GB (SSD)
Screen resolution	1920 x 1080
Scale and Layout	Scale set to 100%
Operating System	Windows 11
Noah	4.16 or higher
Internet browser	Windows-supported internet browser
Ports	USB 2.0 port (or higher)
Sound card	16 bit, stereo, Microsoft DirectSound and DirectSound 3D-compatible

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 behaviour, including loud sounds that may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

Installation

Start the installation by double-clicking the Setup.exe file on the computer with the fitting software and follow the guidance in the installation program.

When the installation program completes, the fitting software can be started from Windows Start menu.

Fitting preparation

The initial screen provides access to features that can help you prepare and set up before starting a fitting session. The features are all accessible without having selected a patient.

Catalog shows available products with detailed lists of features and technical specifications. The page also includes an order link to make it easy to purchase hearing aids directly from the manufacturer.

Fitting contains the **Patient, Instrument Set-Up**, **Gain Adjustment**, **Advanced Features**, **Device controls**, and **Finalise** screens.

Resources has links to feature demos, overview of phone compatibility, user guides, and other learning materials.

Tools contains the **Test Device** and **Restore Instrument** functions. Furthermore, on this page you can find counseling tools, such as **Audiogram Counseling**, **Hearing Loss Simulator**, and **Sound Player**.

Update has links to update Noahlink software, the fitting software as well as accessories.

Preferences enables you to define how the software works best for you.

Start a patient session

With the fitting preparation in place, a patient session can be started by clicking the **Select or Add Patient** button on the **Session** page.

On the next screen, you can choose to work with an existing patient from the patient database or to create a new one. When you select an existing patient, a list of previous sessions display.

To start a session, click the **Fit Patient** button, and then the **Connect** button.

Select programming interface

In the top left of **Assign Instruments**, select the relevant programming interface. Beltone Solus Max works with:

- Noahlink Wireless
- Noahlink
- Speedlink
- Hi-PRO 2

The connection assistance animations demonstrate how to connect specific hearing aid models with the selected programming interface.

NOTE:

- Place Noahlink Wireless on the table with a clear line-of-sight to the hearing aids, which should be within a range of three metres (10 feet).
- 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 between Noahlink Wireless and the PC longer than three metres (10 feet).

Select hearing aids

Hearing aids available for selection will appear on the screen as they are detected. If the hearing aids do not appear immediately, click **Scan**.

Once shown in the list, assign the hearing aids by clicking the left or right button near the appropriate hearing aids, or by pressing the button on the hearing aid itself.

If flex demo devices are detected, they will indicate the highest applicable technology level of the Beltone hearing aid family. This will reflect the true capabilities of the flex demo device.

Start the fitting

To proceed to fitting with the selected aids, click **Continue**.

If FLEX devices are selected, change technology level and then click **Continue**.

If there is session data on the hearing aid or the FLEX device, clear data using the **Reset to initial fit** option in the **Fitting Data Mismatch** screen and then click **Continue**.

Fitting screens

During fitting, the screen has two sections: a vertical navigation pane with patient and hearing instrument information that stays open during the entire fitting process, and a dynamic area that changes according to the vertical menu and submenu choices.

The top menu and the submenu items are described in the sections below.

Tips:

- **Feature Demonstrations** are available from **Resources**. and from the **i** icons next to the features on **Comfort** or **Speech**. The demonstrations typically include both text and short videos.
- If screen space is limited, the left pane with patient information can be closed.

Patient

Select **Profile** and then **Experience Level** to set this based on patient's previous experience with hearing aids. To reduce overall loudness, select **Gain Level (%)** of the prescribed target gains.

Demonstrate where the hearing aids can help the patient, by using the different **Audiogram Overlays** on the **Hearing Loss Simulator** screen available from **Tools.**

Select In-Situ Fitting in the Patient tab to set the gain levels based on an situ-fitting.

Limitations of in-situ fitting

 CAUTION:

- 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

Instrument Set-Up

To change the configuration of the hearing aids, select **Reconfigure**.

 WARNING:

If a hearing aid earpiece is changed, care must be taken to ensure perceived loudness and sound pressure level do not change when going from a more open earpiece to a more closed one. An increase in sound pressure level may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

Feedback Eraser 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.

Gain Adjustments

Enter **Fine Tuning** to

- Adjust hearing aids gain by 1, 2, or 3 dB increments.
- Fine-tune gain settings from the program tabs.
- Mute or unmute the hearing aids.
- Link or unlink the hearing aids.
- Change Prescribed MPO to Instrument MPO.

 CAUTION:

It is not recommended to perform Feedback Eraser calibration under the following conditions:

- If the hearing aid is not inserted correctly
- 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 Feedback Eraser under the above conditions may result in increased calibration output which may exacerbate tinnitus and/or hyperacusis.

Advanced Features

Programs

Use the tabs found above the feature settings to select a program. You can add programs one to four.

Feature settings under **Advanced Features** apply to the currently selected program.

Adjust features that enhance speech understanding. To access additional features, primarily for noise reduction, select **Comfort**.

Device Controls

Adjust beeps and volume settings from **Device Controls**.

Manual Controls include options to

- Enable and disable button functions, including flight mode control, volume control, program switching and Ear-to-Ear communication.
- Configure the push button.
- Configure the maximum volume range to prevent the patient from increasing volume or sound generator output level on the hearing aid; this is done by setting the volume control range to 0.

If TapControl or Hands Free is available for the hearing aids, this is where you can enable or disable it.

Standard Beeps include options to demonstrate, enable, adjust, or disable all acoustic indicators. Low or high frequency beeps can also be selected.

Accessories is used to select and pair accessories. Click **Pair** beneath the accessory you wish to pair. When the accessory is successfully paired, the accessory image will appear in colour with a remove button below.

Finalize

As the name implies, **Fitting Summary** shows a summary of the options selected during the fitting process. Review settings, including the number of programs.

To view and edit reports after the fitting session, go to **Reports**. The reports can be previewed, downloaded, e-mailed and printed and include useful information for the patient.

Use **Save** to save fitting data to the default location; **Save Options** show the default location and enables you to make changes.

CROS and BiCROS fitting flow

Before you begin, ensure that CROS compatible devices have been selected; CROS Transmitter devices are available as a RIE CROS and a BTE CROS.

Enter in the audiogram for both ears - including the worse hearing ear where a minimum of two thresholds are required to proceed with a fitting. A **No Response** is accepted as a threshold.

Detection and connection

Ensure that devices are powered on and not placed in a charger. For devices without detectable receivers, assign each device to the desired side.

- LP, MP, or HP receivers can be used for a RIE CROS Transmitter device; select whichever fits the ear best.
- The RIE CROS Transmitter must be fit with a RIE device on the contralateral ear.
- The BTE CROS Transmitter may be fit with a thin tube or with a hook and standard tube; whichever is preferred.
- The BTE CROS Transmitter may be fit with either a BTE or a custom device on the contralateral ear.

Dome selection

The fitting software can use any dome with the CROS Transmitter; select the dome that provides the best fit and comfort for the patient. Typically, an open dome provides the best comfort on the side that has been fit with the CROS Transmitter.

CROS and BiCROS fitting

There is no need to differentiate between CROS and BiCROS fitting in the fitting software.

Gain for the receiver side is prescribed based on the audiogram and the selected fitting rule.

To overcome occlusion, the microphones are turned ON for the receiver device even in the case of normal hearing in the better ear (CROS fitting).

CROS fitting	Adjust the gain on the receiver side based on the patient's preferences. If the patient prefers less awareness of sounds on the receiver side, consider reducing the negative gain – even into negative values if necessary. If you set the Activate Hearing Aid Microphone toggle to OFF, it will disable the Receiver side microphone. This option removes extraneous noise from the receiver side when the client has normal hearing.
BiCROS fitting	Program the receiver side in the same manner as a standard hearing aid fitting, adjusting gains and advanced features based on patient needs. AutoREM is available for the receiver side.

CROS balance control

The CROS balance control can be found in **Advanced Features**.

The control allows for adjustment of the sound balance of the CROS transmitter relative to the receiver side. You can adjust the CROS/BiCROS balance towards either the transmitter (CROS/BiCROS device) or the receiver (hearing aid) or choose to maintain an equal balance between the two.

Adjust the balance control based on client feedback and probe microphone measurements.

Patient controls

Controls to enable the patient to manage CROS balance are available: the patient can use the short and long button push options for CROS up/down functionality on the transmitter side and volume up/down on the receiver side.

If the patient uses a compatible smartphone for hearing aid control: a CROS balance control and CROS transmitter mute are available in the Beltone HearMax™ app.

AutoREM

The fitting software offers integrated, automatic real ear measurement (AutoREM) functionality.

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

To use AutoREM, you must open the fitting software via Noah and connect the hearing aids. AutoREM is then available under **Gain Adjustments**.

When AutoREM is started, follow the five steps in sequence; each step has detailed on-screen instructions.

Preparation

Select the ear to be measured and ear level hardware to be used from the available menus.

Tube Calibration

1. Place the ear level hardware on the patient's ear while they are 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 centre of the screen to begin the measurement.

Unaided Gain

The real ear unaided gain (REUG) can be determined by measuring the sound pressure level in an open ear canal near the tympanic membrane.

REUG is beneficial to perform because it guides the probe placement and reassures that the mics and probe are not obstructed.

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 (= within 5 mm of the eardrum).
2. Place the patient at appropriate distance and azimuth from the loudspeaker.
3. Click the REUG 70 dB button in the centre of the screen.
4. Compare the Measured REUG to the Predicted REUG.

5. Select whether you want to use **Measured REUG** or **Predicted REUG**.

The average adult will have a primary peak around 2650 Hz with a secondary peak in the 4000-5000 Hz range but will vary according to the physical characteristics of the patient's ear. The **Probe Tube Placement**, when available, is a visual guide to appropriate probe placement. Note that this tool is meant to provide guidance along with visual inspection.

Aided Gain

Aided gain measurements are completed with the probe tube and hearing aid placed in the ear and hearing aid turned ON. The probe microphone measures the sound pressure level in the ear canal while the system compares the levels to target. Adjustments are made to the hearing aid to ensure target is achieved.

Gain curves are the difference between the signal presented from the speaker to that measured at the probe in the canal.



WARNING: The fitting software 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.

To complete aided measurement:

1. Select the type of measurement in Measurement View.

   Vent Accommodation defaults to **On** when a open, or closed dome or vented earmould have been selected as the acoustic parameter with the hearing aid. Select **Off** when the ear coupling has little to no sound leakage, such as with a custom product with medium, small 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.

2. Select the program to be measured.

   Any of the programs fitted prior to entering AutoREM can be used in during verification.

3. Select stimulus to be used during the measurement.

⚠ WARNING: Speech-weighted noise should only be used as a test stimulus if the measurement program has noise reduction features set to OFF. 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 which may damage residual hearing or exacerbate tinnitus and/or hyperacusis.

4. Place the hearing aid into the ear while keeping the probe tube in place.
5. Check the mid-level Match Target box, then select **Run Measurement** to start the measurement. Three attempts, or less will be made to adjust gain to target. Note that all input levels will be adjusted along with the mid level input.

   You can also at this point choose to select other input levels, which will run in sequence following the mid-level input run(s).

   Controls are unavailable when the measurement is in progress.

6. Additional measurements can be made at soft (50 dB) and loud (90 dB) input levels. For the soft and loud inputs either **Quick Run** or **Match Target** can be used.

   Match Target: fine tunes the gain to target.

   Quick Run: option to measure the soft and loud inputs without additional gain adjustment.

   Mix and Match: you can choose **Match Target** or **Quick Run** for soft and loud inputs based on your needs and patient tolerance.

7. Vent Accommodation: renaming of low frequency tolerance setting.

   OFF = will match the entire frequency spectrum within 5 dB of target.

   ON = 750 Hz allows –15 dB roll off; 1 kHz allows –10 dB roll off.

Apply Gain

To apply the adjusted gain to the fitted settings:

1. Select which programs to apply the adjustments. Adjustments can be applied to all programs or the one used during the measurement.
2. Select which ear(s) to apply the adjustments. This selection will immediately apply your changes and a confirmation message displays.
3. Select **Save & Close AutoREM** to return to **Gain Adjustments**. This saves your measurements to the database as a REM session to be documented and reviewed.

Test Device

The fitting software offers the ability to optimally setup the hearing aid so that you can test it in a hearing aid test box and compared to the ANSI/IEC standard.

Place the hearing aid in the test box following the instructions for proper placement provided by the test box manufacturer.

1. In **Tools**, select **Test Device.**
2. Read the **Caution** reminding that the hearing aids should **NOT** be worn on the ear at this time, and proceed by clicking "**I Understand**".
3. Test Device will begin with the Hearing Aids Muted.
4. Choose the test you want to perform from **Select Test Mode**: **Full On Gain**, **Reference Test Gain**, **Fixed Directional** or **Omni Directional**.
5. An indicator in the top left corner in the Right or Left Instrument window will display indicating if the program is loading or testing (sound is being presented from the hearing aid).
6. The hearing instrument can be muted at any time by selecting **Muted** from **Select Test Mode**.
7. To perform **Full On Gain** or **Reference Test Gain** with the telecoil, turn the telecoil toggle on (indicated by toggle turning green). Note that Directional options are NOT available with the telecoil.
8. Once testing is completed, click **Finish Testing**. The hearing aids are restored to user or manufacturer settings.

Remote fine-tuning

This section describes options in the software to manage fitting sessions with patients who are not physically in the clinic.

Remote fine-tuning does not require you to be online at the same time as the patient. The patient needs to have the Beltone HearMax™ app installed on their phone.

Note that feature availability will vary by product family and technology level. The features described below may not apply to your product.

WARNING: Use of remote fine-tuning 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:

- Visible, congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- 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 the tinnitus perception, discomfort or interrupted speech perception, while using the tinnitus sound generator.

Preparation for using remote fine-tuning

Prior to using remote fine-tuning for the first time, the patient's consent is required. You can either manage this during a normal consultation or in a phone call. The patient consent form is available from the app; the form has options that describe data, and the way data is managed. The patient needs to agree, and the completed form needs to be shared with the patient and kept in the patient's records.

Make sure that the hearing aids are connected to the fitting software as described previously.

Click the user icon in the top right of the screen to sign in to online services and your name will appear next to the user icon.

Enable remote fine-tuning from **Patient**: select **Beltone Remote Care** and select **On** for **Remote Fine-tuning**.

The Windows taskbar has an online services cloud icon that notifies you of any incoming request for assistance. We recommend that you make sure that the icon is visible on the taskbar when you have enabled remote fine-tuning in the fitting software.

Handle an assistance request from a patient

Click the cloud icon to see requests received and then click **New Request** to handle a request.

The menu option **Open Solus Max** opens the timeline for that particular patient. The menu option **Remove from List** deletes the request from the notifications, but it still appears on the patient's timeline.

Start a fine-tuning session from the timeline

When the assistance request appears on the patient's time, click **Actions** and then **Start**. A pop-up message appears stating that the selected session will be used as the starting point for the session. Click **OK** to continue.

View patient's assistance request questionnaire

The patient's assistance questionnaire sent from the app can be opened from the patient pane on the left. When opened here, the questionnaire can be moved around the fit screen during fine-tuning adjustments.

Alternatively, the questionnaire can be opened from the actual request.

View patient's preferred settings

Click **On** for **View Patient Settings** at the bottom of **Gain Adjustments**. This will make it possible to see the patient's preferred adjustments to settings in the app.

In **Gain Adjustments**, patient settings are shown in green.

In **Advanced Features**, patient settings are shown as grey dots on the settings.

Fitting adjustments can be made from this information as well as from the questionnaire.

Having made the necessary adjustments, click **Save** in the lower right corner of **Gain Adjustments**.

Send update and close request

When you have made the required adjustments and saved in **Gain Adjustments**, click **Send Settings** in the lower right corner. In the free text field that opens, you can write a message to the patient and include a summary of changes if desired. Click **Send Settings** again.

A summary of the actions taken can be viewed in the patient timeline.

After sending the package, go to the patient timeline to close the request. The patient can have a maximum of five open requests in the app and only you can close them.

Alternatively, you can close requests from GN Online Services on https://portal.gnonlineservices.com.

Send a remote fine-tuning without an assistance request

You can send a remote fine-tuning to a patient without having received an assistance request.

Sign in to online service and then:

1. Open the patient's data on **Gain Adjustments**.
2. Follow the standard fitting flow.
3. Save the fitting.
4. Choose **Send Settings** as described above.

The patient will receive the package in the app, and the remote session appears on the patient's timeline.

Live remote assistance

This section describes options in the software to provide live remote assistance to patients who are not physically in the clinic.

Live remote assistance is a call with the patient that is initiated from the software.The patient needs to have the Beltone HearMax™ app installed on their phone.

NOTE: The programming interface for live remote is Weblink, but it is required to have Noahlink Wireless plugged in.

Live remote assistance functionality is not enabled by default. For more information about access, contact your local Beltone representative.

WARNING: Live remote assistance 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.

Live remote assistance 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 live remote assistance leading to gain levels that can damage residual hearing or exacerbate tinnitus and/or hyperacusis.

The use of live remote 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:

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

CAUTION: Use of live remote 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.

WARNING:

The use of live remote assistance 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 an adjustment of gain levels that can damage residual hearing or exacerbate tinnitus and/or hyperacusis.

Preparation for using live remote assistance

Click the user icon in the top right of the screen to sign in to online services and your name will appear next to the user icon.

Enable remote fine-tuning from **Patient** by selecting: select **Beltone Remote Care** and select **On** for **Live Assistance**.

The patient must have their hearing aids paired with their smartphone and Beltone HearMax™ app installed. They do not need to have the app open to receive the call.

NOTE: If you are using live remote assistance for remote fitting, see this section with additional guidance: 'Detailed steps for live remote assistance'.

Initiate the call

Start the fitting software in simulation, following the same first steps as in remote fine-tuning.

In the patient panel to the left, click the **Start Live Assistance** button to start the call with the patient.

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

Perform live remote fine-tuning

To connect to hearing aids click **Connect** in the **Connect Devices** dialog box that opens automatically.

The patient hears your voice through their hearing aids until the hearing aids are connected to fitting software. When connected to the software, your patient will hear your voice through the phone's speaker instead of the hearing aids.

If you click the **Simulate** button rather than the **Connect** button in the **Connect Devices** dialog box, you still can connect to the hearing aids in the panel on the left side of the screen.

Note that your changes in simulation will be transferred to the patient's hearing aids once you connect to them.

In the 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 a live assistance session:

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

When you have finished, 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 do further adjustment 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.

If the patient ends the call, you will be notified in the fitting software.

Detailed steps for live remote assistance

This section is a detailed step-by-step description of live remote assistance, including remote fitting using in-situ testing.

A live remote assistance appointment should be treated like as a normal in-clinic hearing aid fitting. All normal procedures conducted at these visits should be conducted through live assistance.

Hearing aid styles for remote fitting using in-situ testing

Receiver-In-the-Ear (RIE):	• For new patients: Only LP receiver, MP receiver or MM receiver • For existing hearing aid patients only: LP receiver, MP receiver, HP receiver, UP receiver or MM receiver
Behind-the-Ear (BTE) – for existing hearing aid patients only:	• BTE with standard 2 mm tubing

NOTE: Patients currently wearing a BTE with thin tube must be fitted with a RIE hearing aid instead.

Super Power models are not supported.

The following guidance is recommended when you perform a remote fitting of a new hearing aid using in-situ testing together with live assistance. The guidance is designed to ensure the accuracy of the fit and safety of the client.

NOTE:

- The guidance assumes that national as well as other regulations and guidance for hearing aid fitting are followed, for example medical evaluation and reimbursement regulation.
- For the US: Ensure that you remain familiar 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 remote medical evaluations and the practice of remote care across state lines.

- The guidance is relevant in remote fitting cases where a valid audiogram for the patient exists on file.
- The guidance also describes situations where no audiogram is available or only an outdated is available and in-situ testing is therefore used to fit the hearing aids.
- The patient can be a new patient or an existing patient using aids.

⚠ WARNING:

- Instructions provided in this document for choice of product range and hearing aid style must be followed.
- 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.
- Before shipment to the patient 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 patient to respond to tones during in-situ test.
- In-situ test shall be done at a quiet place.

⚠ CAUTION:

- 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.
- Domes can get detached and stuck in ear canal. If they are not removed promptly, it can cause damage to tissue in the ear canal.
- LP or MP receivers must be chosen for first-time patients.
- Too short a receiver wire/thin tube 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 or prepare to do remote fitting using in-situ testing.
2. Prepare your patient.
3. Prepare the hearing aids: Fit and assemble the hearing aids before delivering to your patient.
4. Prepare your live assistance setup.
5. Check that the patient is ready to receive the live assistance call: the patient must download the Beltone HearMax™ app and connect it to the hearing aids. Also, the patient must consent to using online services in the app.

6. Conduct the live assistance call with the patient.
7. Set up a follow-up meeting in the clinic.

The following section describes each of the steps in detail.

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

Retrieve the patient from the Noah database and verify the validity of the audiogram. This should be done for both new and existing patients.

If a valid audiogram does not exist on file for the patient, prepare to do remote fitting using in-situ testing.

Step 2: Prepare your patient

1. Schedule a phone or video call with the patient to provide instructions and confirm physical health of the outer ear and ear canal.

   Ask the questions in the list below. If the answer is "yes" to any of the questions, refer the patient for medical evaluation prior to fitting the hearing aids.

   Does the patient exhibit or report:

   - Visible congenital or traumatic deformity of either ear?
   - Active drainage from ear(s) within the last 90 days?
   - Sudden or rapidly progressive hearing loss, unilateral or bilateral, within the last 90 days?
   - Acute or chronic dizziness?
   - Sudden onset or increase in severity of tinnitus within the last 90 days?
   - Pain in the ear(s)?
   - Evidence of cerumen accumulation or foreign body in the ear canal(s)?

   In addition, the free CEDRA questionnaire can be used:
   https://cedra.northwestern.edu/ (available in English only).

2. Confirm that the patient has a compatible mobile phone.
3. Notify the patient that you will send hearing aids to them.

   Confirm that the patient can receive/pick up the hearing aids.

4. Notify the patient that you will be sending information by email:

   Use the provided email template to obtain consent for GN Online Services.

   For curb-side pick-up, a printed copy of the consent form can be prepared for the patient to sign.

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.

Step 3: Prepare the hearing aids

1. Ensure you are using the latest version of the fitting software.
2. Choose the appropriate hearing aids and power level for the patient based on the audiogram on file.
   - For new patients: Choose a RIE hearing aid with either LP or MP receiver.
   - For existing patients: Choose one of the hearing aids listed above under '**Product range**' and '**hearing aid styles**' based on the audiogram on file.
3. Verify that the hearing aids meet ANSI specifications using a test box.
4. Open the patient's file in Noah.
   - 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 the standalone fitting software.
   - For existing patients: No changes to the audiogram on file need to be made.
5. Set or check the experience level.
   - For new patients: Choose a conservative experience level, either '**First Time User**' or '**First Time User-Onboarding**'.
6. Connect the hearing aids to the fitting software and open **Gain Adjustments**.

   Fit the hearing aids:

   - For existing patients, use the audiogram and other patient information on file as the basis of the first fitting

   Sign in to GN Online Services (in the top right corner of the screen).

7. Verify that **Remote Fine Tuning** and **Live Assistance** are enabled.

   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.

8. Save the settings in the hearing aids and exit the fitting software.
9. Before packaging the hearing aids, ensure assembly of the hearing aids. Attach any receivers/tubes and the selected domes or moulds:

For RIE/thin tube BTE hearing aids:

Attach receivers/thin tubes:

- Determine receiver power by comparing the patient's hearing loss to the fitting ranges in the fitting software.
- For new patients: Choose an LP or MP receiver with a wire length of medium size. If in doubt, choose a longer receiver length to avoid too tight a 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.

Attach domes for fitting:

- For new patients, or patients shifting to RIE/thin tube BTE hearing aids: Choose tulip domes. Domes can be changed at the follow-up in-clinic 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 too big a dome.

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 (in-situ tones being played louder) and result in an incorrect in-situ result, which can lead to gain being set too high.

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 the 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 too big a dome.
- For all patients: Include at least four extra domes. Different dome sizes/types can be included for the client to exchange, with proper instruction.

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

Attach tubing and moulds.

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

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

10. Mark the page in the patient guide that demonstrates insertion and removal of the hearing aids, as well as care and maintenance of the hearing aids. For RIE and thin tube BTE hearing aids, also mark pages with dome attachment.
11. Depending on which model of hearing aid is being fitted, verify that the hearing aids are fully charged (if rechargeable) or include an ample supply of batteries.
12. Deliver the hearing aids to the patient. Notify the patient of the tracking number, if relevant and available.

Step 4: Prepare your live assistance setup

1. Verify web camera and microphone are working.
2. If real-ear equipment is used in the clinic, 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 they are ready to receive the live assistance call and that the following is in place:

- The Beltone HearMax™ app has been downloaded and installed.
- The patient has connected the hearing aids to streaming.
- The patient has connected the hearing aids to the app.
- The patient has accepted access for the app to the mobile phone camera and microphone.

It is important that the patient is wearing 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.

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: Conduct the live assistance call with the patient

Only you can initiate a live assistance call.

1. Open the patient's file in Noah and choose **Simulate** in the bottom right corner, then proceed to **Gain Adjustments**.
2. Sign in to GN Online Services.
3. Select **Start Live Assistance** in the left navigation panel.
4. Make sure the patient can hear through Live Assistance.
5. Check that the physical fit of the hearing aids is appropriate.
   - Before conducting in-situ testing, ensure that the HA fits properly and comfortably.
   - 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.
   - Observe the patient through video to ensure that they have inserted the hearing aids with the power domes correctly. Ask the client to turn to their side to the phone/camera, so you can see their ears and the hearing aids.
   - For curb-side pick-up, you can check the physical fit on the patient before leaving.
6. Connect the hearing aids.

   If the session is with a new patient and in-situ testing is to be used, go through the sub-steps below; otherwise go to the next step.

   - Instruct the patient to be in a quiet place for the in-situ testing and explain how they should respond to the in-situ signals when heard (for example, hand raise, verbal response – choose most appropriate).

   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.

   For existing patients where an audiogram exists on file: use in-situ as a quick check to ensure hearing has not changed before proceeding to fit.

   - Save in-situ test results and choose **Apply to fitting**.

   Before moving on to the fitting, verify that the fitting range of the chosen hearing aids and dome/mould are appropriate for the patient.

   Once in-situ testing is complete, the patient will need to remove the power domes and attach the domes provided in the package.

Refer the patient to the marked page in the user guide for how to change the domes and demonstrate over the video call with similar devices so that the patient can see it done in real-time before the patient does the change

7. Instruct the patient to remove the hearing aids if the sound is uncomfortable during the fitting.
8. Calibrate the feedback reduction system (Feedback Eraser).
9. Make programming adjustments like a normal session.
   - For new patients: Ensure that a conservative experience level has been selected, either '**First Time User**' or '**First Time User-Onboarding**'.
   - For existing patients only: Adjusting Tinnitus Breaker Pro:

     Tinnitus Breaker Pro (TBP) cannot be activated for initial fittings via live assistance. Initial activation of TBP must take place at an in-clinic visit. Transfer of TBP settings from a previous hearing aid is not considered an initial fit, as the patient has previously been fitted with TBP at an in-clinic visit.

     Live assistance can be used to adjust TBP for a patient who had it activated in an in-clinic fitting. For US only.

10. Save the fitting and disconnect the hearing aids. This will apply the fitting to your patient's hearing aids.
11. 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 hearing aids, correct assembly of dome and receiver, charging/changing batteries, cleaning, care and maintenance, and expectations for daily use.

    All the above steps can be demonstrated over the video call using the same hearing aids and tools as in the clinic.

    Again, use a similar set of hearing aids to demonstrate on the call.

    Also refer to the instructions described in the patient guide accompanying the hearing aids.

    Patients should be encouraged to keep a daily journal to track their usage of the hearing aids and to document their experience with them.

12. Schedule a follow-up live assistance call within 48 hours of the fitting.

Step 7: Set up a follow-up meeting in the clinic

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

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.

For existing patients: At the follow-up visit, conduct a full audiogram along with REMs and fine-tuning adjustments.

View ratings from patients

In the app, patients can give feedback on the sound they experience. This means that the feedback can be given when patients are in the listening situations.

When a fitting or fine-tuned settings have been rated by the patient, you receive an email notification.

The rating can be viewed within the timeline. If the patient sent an assistance request with the rating, the request appears as the latest action in the timeline and the rating is listed below it.

If you want to generate a new set of fine-tuned settings, follow the steps in the 'Start a fine-tuning session from the timeline' section.

Tinnitus Breaker Pro

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 section is designed to serve as suggested starting points and can be modified as needed for individual patients.

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

Intended use / indications for use of TBP

The Tinnitus Breaker Pro Module is a a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

The Tinnitus Breaker Pro module is targeted at healthcare professionals who are treating patients suffering from Tinnitus, as well as conventional hearing disorders. The initial fitting of the Tinnitus Breaker Pro module must be done during an in-office visit by a hearing professional participating in a Tinnitus Management Program. [1]

Target population for TBP

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. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing healthcare professional or the guardian for the insertion and removal of the hearing aids.

Tinnitus Breaker Pro is available from the **Advanced Features**.

Default Programs

- P1-All Around

  NOTE: Directionality settings are CrossLink Directionality 4 for binaural fittings, Speech Spotter Pro for monarual fittings; Directionality settings are different for technology levels 9 and 6.

- P2 – Hear in Noise

NOTE:

- The Tinnitus Breaker Pro (TBP) features are the same in all technology levels and can be activated in any program.
- The TBP volume slider is in dB SPL. The TBP settings and audiogram can be displayed in dB SPL or dB HL.
- The binaural link option is not available in the TBP 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).
- Settings for Mic relative to TBP balance, Synchronization and Volume Control impact both Standard TBP and Nature Sounds.

[1] If deemed feasible by the hearing professional, subsequent fittings of the Tinnitus Breaker Pro module may be performed remotely and in real time while having live communication via live audio, video and chat on the user's dedicated app.

- Find the information about how long TBP can be used in the Warnings and Cautions section.

TBP activation

1. Select the program you want to use with TBP.
2. Select the **On** option to activate TBP with the selected program.

Set TBP volume

Set the TBP 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 in the sound generator output level. To do so, configure the **High Range Volume** to '0' in the **Manual Controls screen**.

Below is a suggestion on how to first fit TBP. It uses the threshold of audibility as a starting point.

Find the TBP threshold of audibility in three steps

1. Using the volume slider, turn up the volume until the patient reports that they can just barely hear the TBP white noise. This is the TBP threshold of audibility.
2. Increase the volume slider until the patient reports they can no longer hear their tinnitus over the TBP sound.

   This is the level at which their tinnitus is completely masked. This is the minimum masking level (MML).

3. Set the volume 5–10 dB above the threshold level.

   You can go higher than 10 dB if necessary, but do not completely mask the tinnitus signal. This is where the MML is important.

Set the TBP bandwidth

TBP defaults to a broadband white noise setting. There are four sound pre-set options to choose from. They can be customised using the range option to adjust the frequency shaping.

NOTE: Any change in volume or frequency shaping setting will default the sound pre-set to a 'Custom' label.

Customise the TBP features

Amplitude Modulation can be activated if the patient finds it to be comfortable.

Amplitude Modulation causes the TBP 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 between fluctuations.

Turn Synchronization **On** to enable ear-to-ear communication. Then any change to TBP features in one hearing aid, automatically repeats in the other.

Customise volume control options

The **Stimulus Level** options determine how the volume of the TBP will be controlled.

Selecting **Stimulus Level** will reassign the function of the manual volume control to the TBP only for that program.

Selecting **Stimulus Level + Environment** will combine the use of these two features. It also allows manual volume adjustments while the **Environment** features are active. **Environment** allows manual control over the volume as well as automatic volume controls based on the environment loudness.

Activating nature sounds

Nature sounds can be used as an alternative to the standard TBP.

1. Enable **Nature Sounds**.
2. Activate the desired nature sound from the 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 identical nature sounds.
4. **Show Advanced Settings** displays options available for adjustment.

Advanced settings

Advanced Settings enable 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

Program and save

To program the hearing aids and save to Noah, click **Save**.

For more options, click **Save Options**.

When TBP has been enabled in a patient's hearing aids, the patient's app includes tinnitus features.

General warnings and cautions

⚠ WARNING:

- When connected, the fitting software controls the acoustic amplification levels in a hearing aid. In some acoustic environments, over amplification can cause discomfort and damage to the patient's hearing.
- The fitting software 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 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 obtain hazardous risk levels.
- The fitting software 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 shown to give inaccurate estimates of max. stable gain. The risk is that, under some situations, the fitting software 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 hearing aid could cause feedback without warning.
- The fitting software uses the Audiogram+ algorithm to interpret audiogram data for determining optimal gain settings. The parameter used is “first time user”. 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 software uses feedback calibration measurements to compute Max 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. The Feedback Guard (or Feedback Shield) gives a “close” approximation of the actual feedback border. However, it is an estimation and feedback can occur before the border is crossed or approached the warning is given. Sustained feedback on high power hearing aids can damage residual 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.



WARNING:

Warnings for high dB hearing aid (over 132 dB)

- Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level (maximum OSPL90) of 132 dB SPL or higher (IEC 60318-5:2006) as there may be a risk of further impairing the remaining hearing of the hearing aid user.



CAUTION:

- The fitting software will apply recommended amplification settings based on available audiometric information. Settings will be specific to each fitting.
- Manual modification of the fitting parameters will impact and change the amplification level prescribed. 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 aid 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 a PC

⚠ CAUTION:

- 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 and anti-virus software should always be enabled.
- Always be on latest Windows Service Packs/ Updates.
- Always have a healthy scepticism about received external emails.

Pay special attention to seemingly sincere e-mails which try to trick you to give away personal or confidential information such as your user ID and passwords, or which are trying to make you do unwanted actions - such as clicking on an attachment or a link. The concept is called 'Phishing'.

Tinnitus Breaker Pro warnings

⚠ WARNING:

Special care should be exercised in selecting and fitting hearing aids utilizing Tinnitus Sound Generator. The maximum output of the tinnitus sound generator feature falls into the range that can cause hearing loss according to OSHA regulations. For further details please consult the user guide of the relevant hearing aid that includes the Tinnitus Sound Generator feature.In accordance with NIOSH recommendations the patient should not use the sound generator for more than eight (8) hours a day when this is set to a level of 85 dB SPL or above. When the sound generator is set to levels of 90 dB SPL or above the patient should not use the sound generator 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:

- Visible, congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.

- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- 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 live remote assistance feature for remote settings of the Tinnitus Breaker Pro should only be performed by the parent or legal guardian in cases where the patient is a minor.

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

Symbols

The symbols below are used in this user guide, on the device, or on the packaging.



WARNING: Points out a situation that could lead to serious injuries.



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



Legal manufacturer.



Date of manufacture.



Follow instructions for use. (Logo in blue)



Regulatory compliance mark for EU with notified body number.



Medical device.



Unique Device Identification.



Follow local regulations when disposing of electronic devices.

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CE 0297 Any serious incident that has occurred in relation to the device should be reported to the Legal manufacturer GN Hearing A/S and the competent authority of the EU Member State in which the user and/or patient is established.

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