

Interton GN

User guide

Interton Fitting



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How to start

System requirements

Before installing Interton Fitting, 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.

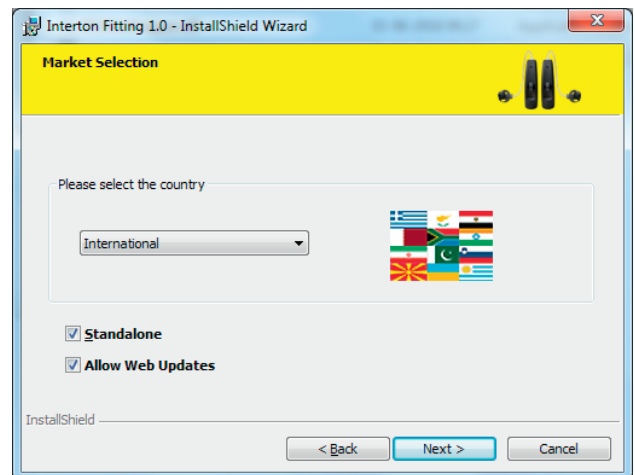
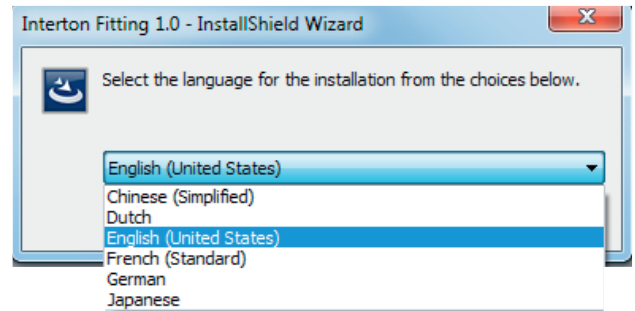
SUPPORTED OPERATING SYSTEMS
<ul style="list-style-type: none">Windows 7 - 32 & 64-bit - All service packsWindows 8 - 32 & 64-bit - All service packsWindows 10 - 32 & 64-bit - All service packs Windows XP & Windows Vista are not supported.
SUPPORTED CLIENT DATABASE
<ul style="list-style-type: none">Noah 4 Noah 2 or Noah 3 are not supported.
SUPPORTED PROGRAMMING INTERFACES
<ul style="list-style-type: none">Noahlink WirelessSpeedlinkNOAHlinkHi-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 Interton products. Please follow the instructions on Interton Fitting.

PC REQUIREMENTS	MINIMUM PC REQUIREMENTS	RECOMMENDED PC REQUIREMENTS
Processor	1 GHz processor (or higher)	2 .93 GHz processor (or higher)
RAM	4 GB	8 GB
Free Hard Disk Space	6 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 - 32-bit (SP1 or higher)	Windows 7 Pro - 64-bit (SP1 or higher)
Noah	Noah 4.6	Noah 4.9 (or higher)
Internet Browsers	<ul style="list-style-type: none">Internet Explorer (IE) - version 10 (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	

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.

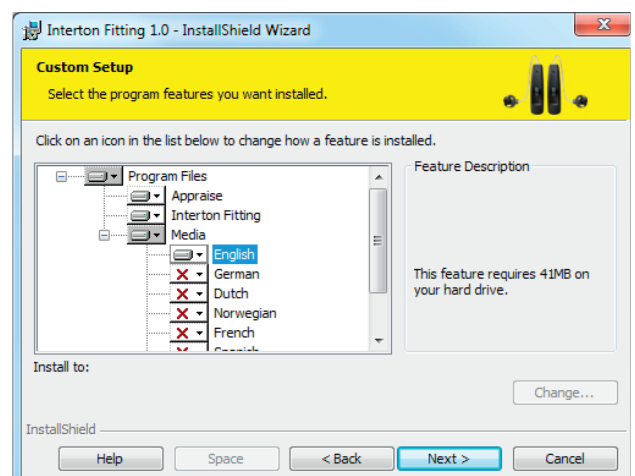
Installation steps

1. Start installing Interton Fitting 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".

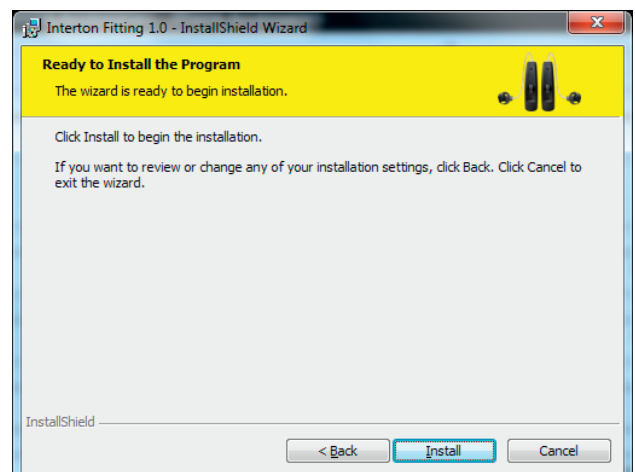


4. Relevant speech files are selected based on the selected market. Click "Next" to start the installation.

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



5. Complete installation of Interton Fitting by clicking "Finish".

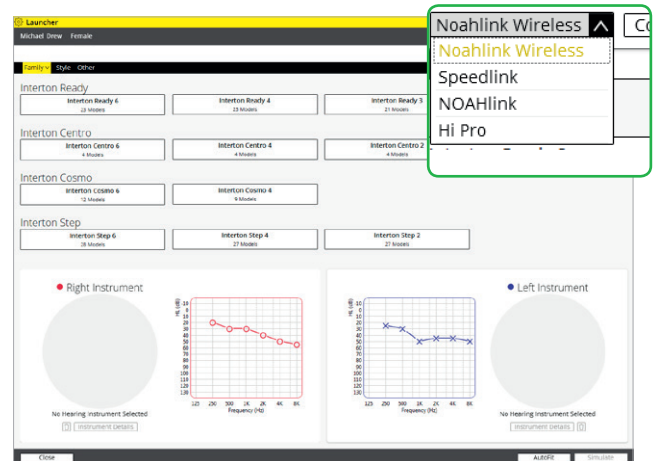


Programming Interfaces

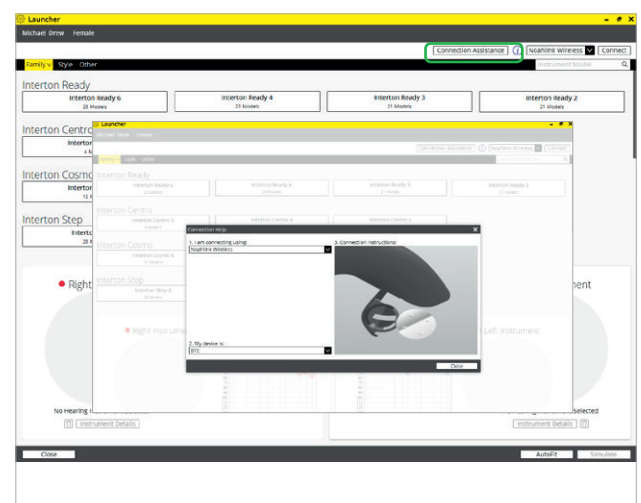
Interton Fitting works with:

- Noahlink Wireless
- Speedlink
- NOAHlink
- Hi-PRO

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

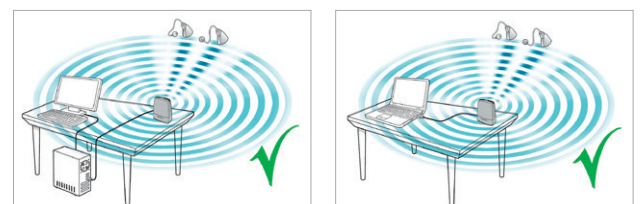


Animations in "Connection Assistance" shows how to connect specific models of hearing instrument(s) with the selected programming interface.



Noahlink Wireless placement:

- Place Noahlink Wireless on the table with a clear line-of-sight to the hearing instrument(s), which should be within a range of 10 feet (3 metres).
- Do not place Noahlink Wireless in a USB hub with other USB devices.
- When fitting hearing instrument(s) 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 10 feet (3 metres).



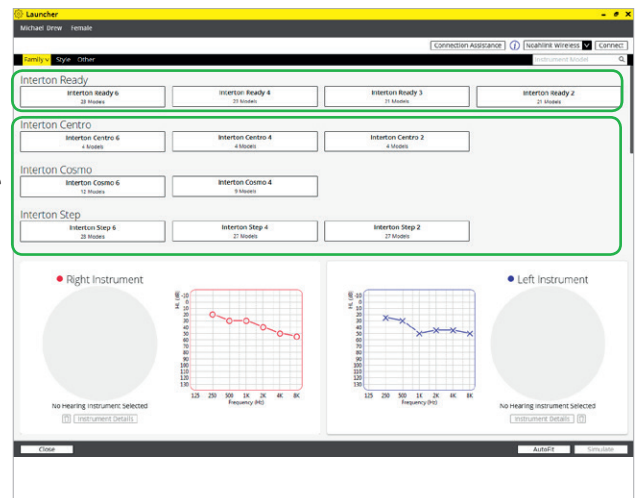
Good to know

Launcher

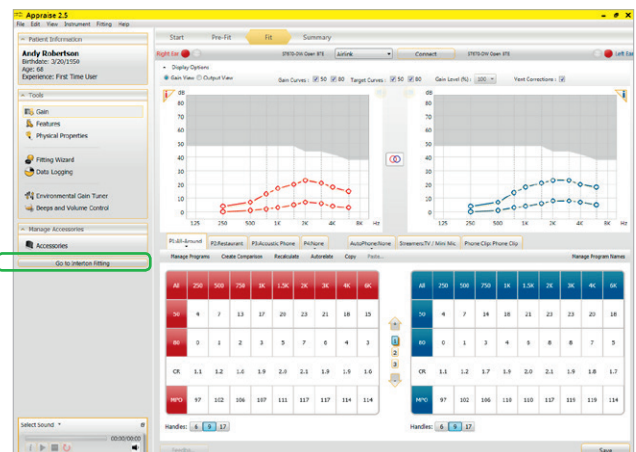
The Launcher contains all of the product families found in both Interton Fitting and Interton Appraise fitting modules. The Launcher automatically opens the fitting software module that supports the connected or simulated instrument(s).

Interton Fitting

Interton Appraise



Note: When you open a session previously saved with Interton Appraise 2, or when you connect hearing instrument(s) previously programmed with it, you are automatically directed to Interton Appraise 2 fitting module. To upgrade your patient's existing Interton hearing instrument(s) to the newest, go to Launcher by clicking on the "Go to Interton Fitting" button in the left side panel of Interton Appraise 2.

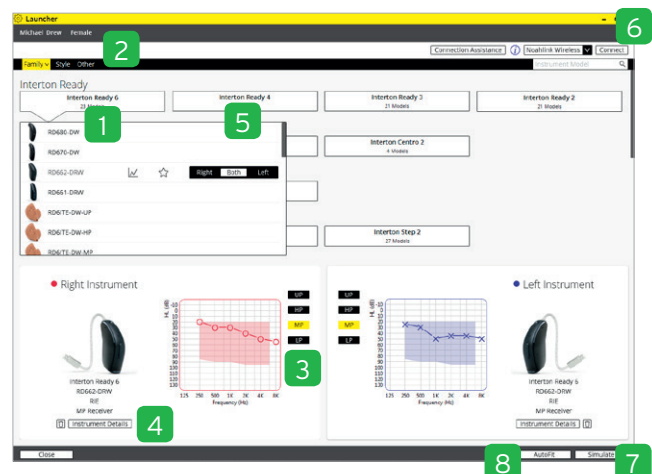


Product selection

1. Product family selection in Launcher - here you can view all available products per family.
2. "Instrument 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 suits your patient's individual audiogram.
3. Fitting range and patient audiogram.
4. Technical details on the selected hearing instrument(s).
5. For simulation, select the hearing instruments to the relevant ear(s). Connected hearing instruments will be assigned as part of the connection flow.

To proceed to fitting with the selected instrument(s), continue with one of the following options:

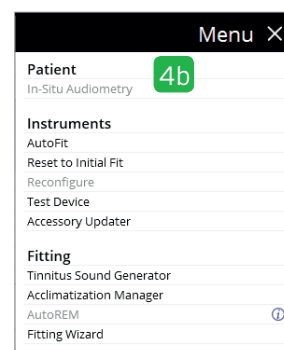
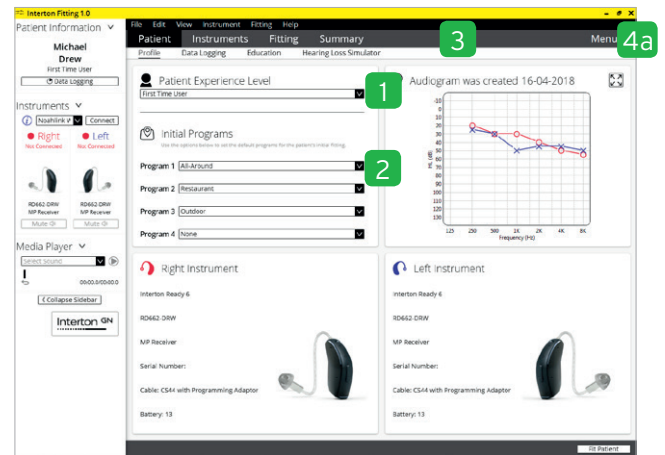
6. Connect.
7. Simulate.
8. Use "AutoFit" to be guided through the fitting steps.



Patient screen

After launching Interton Fitting you will see the "Patient" screen in the grey ribbon on top.

1. For an optimized gain prescription, select the patient's experience level with hearing instrument(s) based on the amplification history, in "Profile" screen.
2. Interton Fitting recommends the program default. You can also select them manually, based on your interview with the patient.
3. Demonstrate where the hearing instrument(s) can help the patient, by using the different "Audiogram Overlays" in "Hearing Loss Simulator" screen.
4. To begin in-situ audiometry using the hearing instrument(s):
 - a. Open "Menu".
 - b. Select "In-Situ Audiometry".

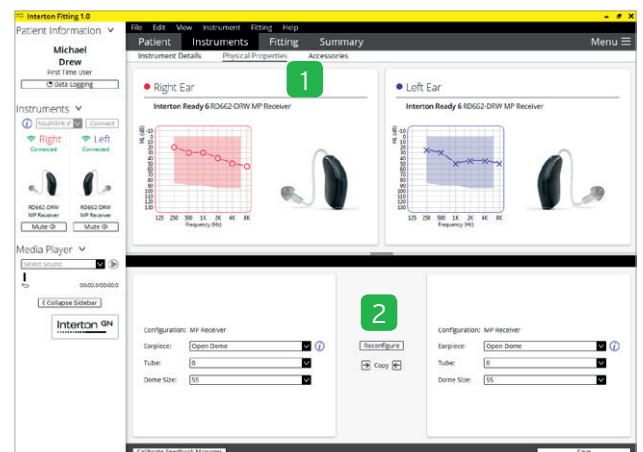


Instruments screen

Physical Properties

To reconfigure the hearing instrument(s):

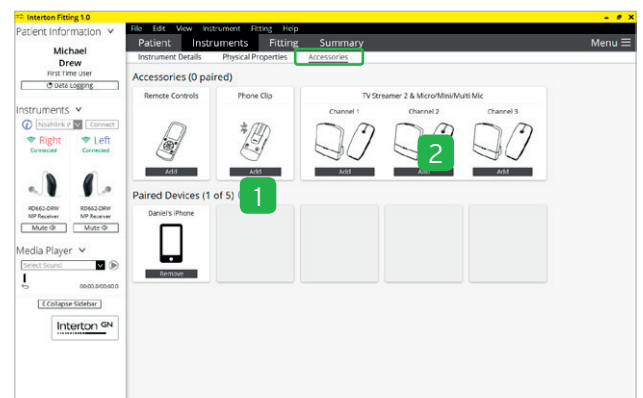
1. Select "Physical Properties" tab.
2. Select "Reconfigure".



Accessories

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

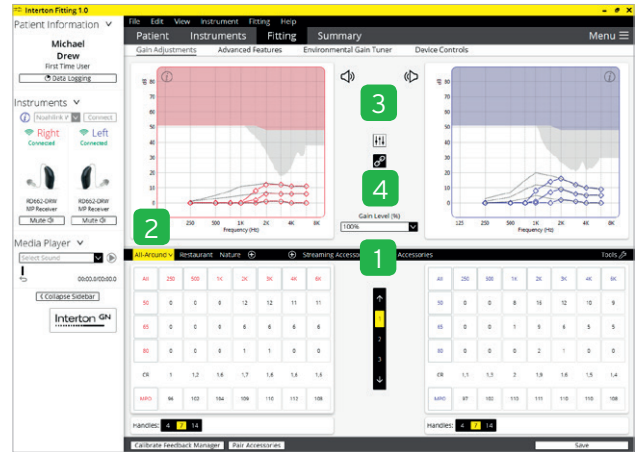
1. Click "Add" beneath the accessory you wish to pair.
2. When the accessory is successfully paired, the accessory image will appear in color with a remove button below it.



Fitting screen

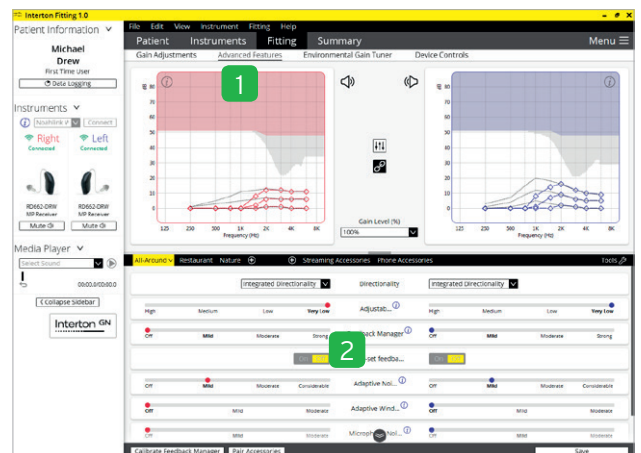
Gain Adjustments

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

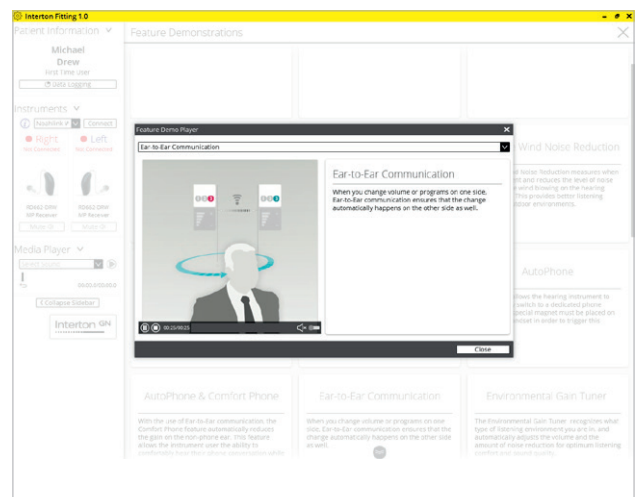
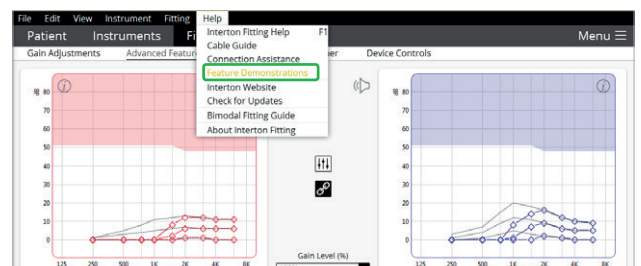


Advanced Features

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.

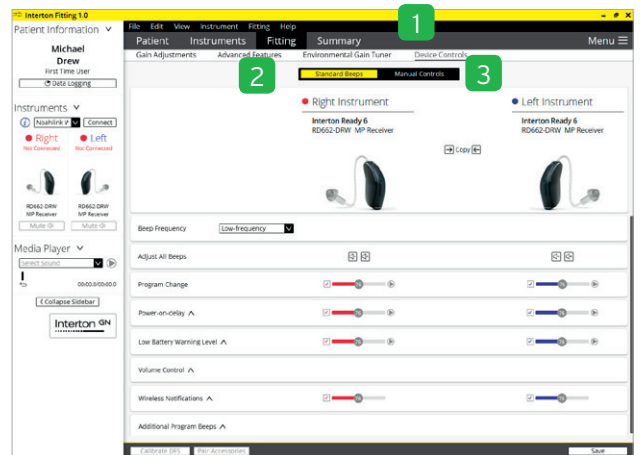


"Feature Demonstrations" illustrate the features available in the hearing instrument(s). You can find the animations by clicking on the ⓘ next to each feature, or in "Help" menu.



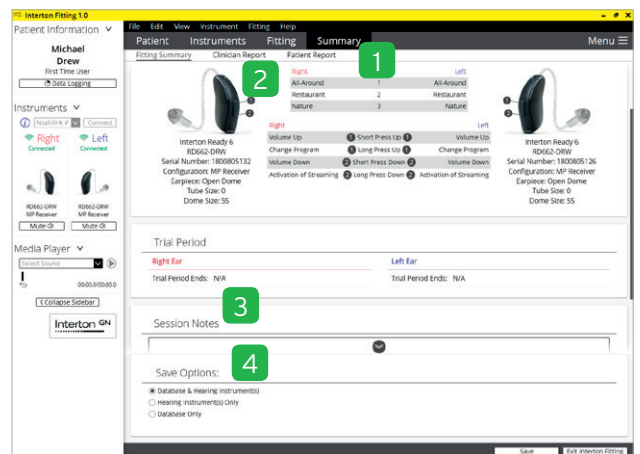
Device Controls

1. Adjust beeps and volume settings by selecting "Device Controls".
2. In 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. "Manual Controls" tab has options such as customizing button function, 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 volume or sound generator output level on the hearing instrument by adjust the High Range Volume to 0.

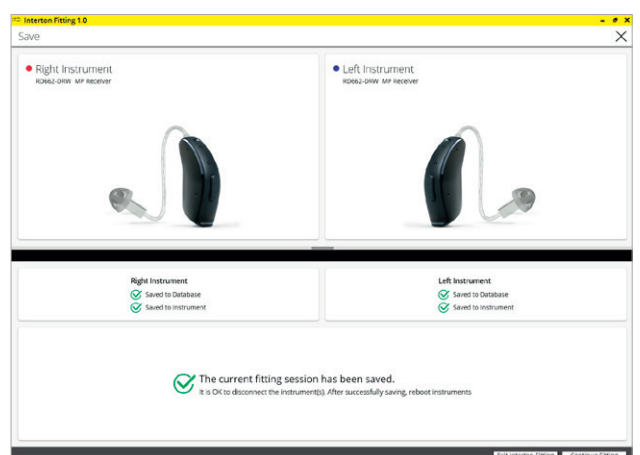


Summary screen

1. Confirm 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 instrument(s).



Tinnitus Sound Generator

This guide assumes a fitting with a multi-program wireless hearing instrument 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 of TSG

The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to 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 5 years of age or older. The Tinnitus Sound Generator module is targeted for healthcare professionals, which are treating patients suffering from Tinnitus, as well as conventional Hearing disorders. The fitting of the Tinnitus Sound Generator module must be done by a hearing professional participating in a Tinnitus Management Program.

Target Population for TSG

The target population is primarily over 18 years of age. But it also can be used with children down to 5 years old. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of hearing instrument(s).

Default Programs

- P1 - All Around
Note: Directionality settings are Integrated Directionality for binaural fittings, Auto-steered Directionality for monaural fittings; Directionality settings are different for technology levels 2, 3 and 4.
- P2 - Restaurant

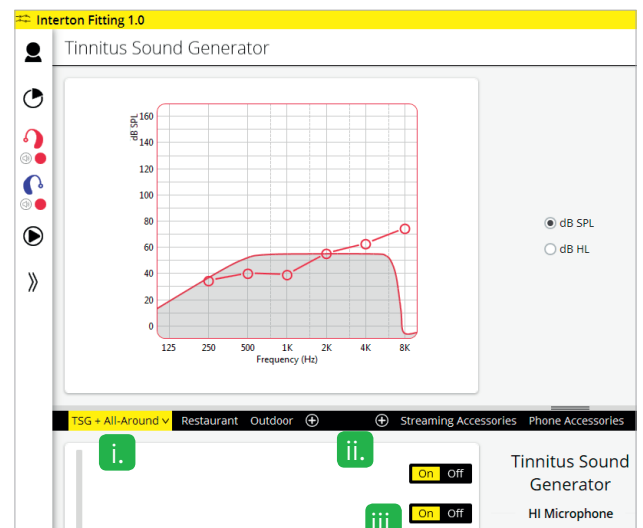
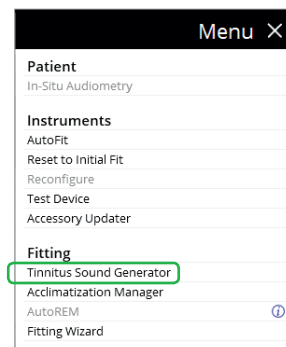
Select “Tinnitus Sound Generator” from “Menu” to start activating and fine tuning TSG.

1. TSG Activation:

- TSG in combination with Amplification program
- Click “On” option to activate the TSG in combination with the selected program.
- TSG only
While TSG is on, turn off HI Microphone to deactivate amplification.

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 in page 12).
- Settings for HI Microphone, Synchronization and Volume Control impact TSG.
- Please find the information about how long TSG can be used, in General Warnings section.

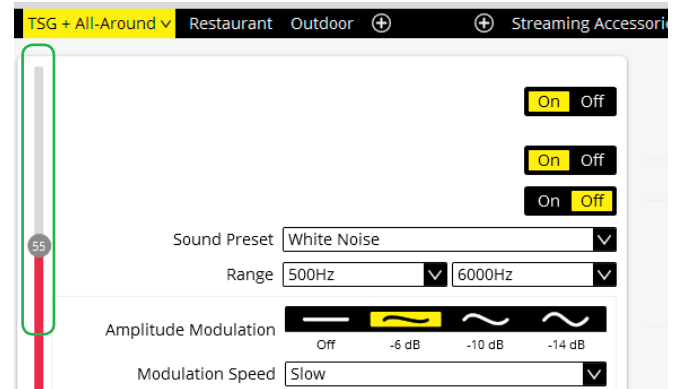


2. TSG volume

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 users, 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. 9). Below is a suggestion on how to first fit the TSG. It uses the threshold of audibility as a starting point.

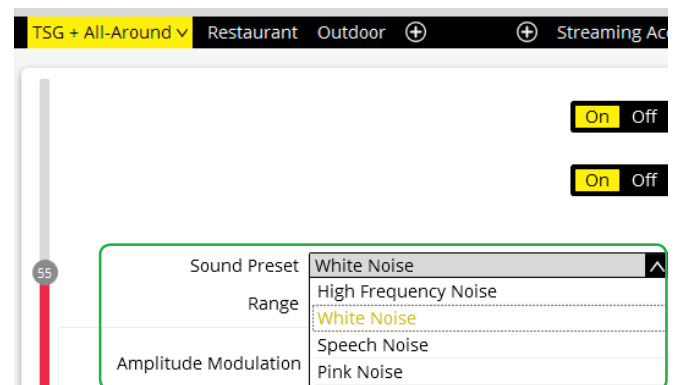
Find the TSG threshold of audibility (three steps)

- 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 threshold of audibility.
- Increase the volume slider until the patient reports they can no longer hear their tinnitus over the TSG sound. This is the level at which their tinnitus is completely masked. This is the minimum masking level (MML).
This is the level at which their 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.



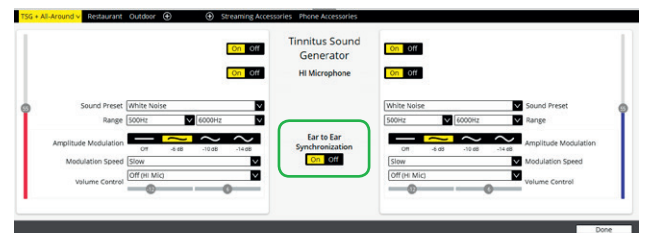
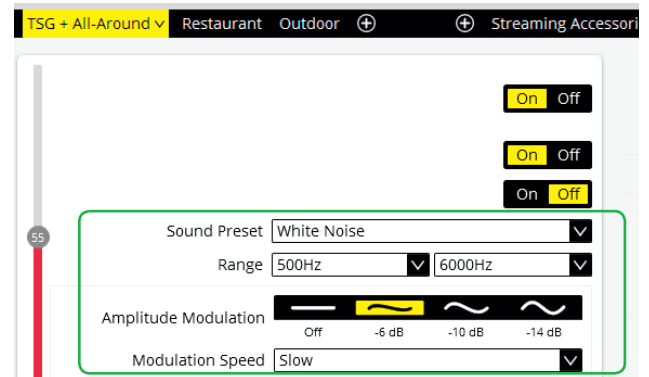
3. Set the TSG bandwidth

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 volume or frequency shaping setting will default the sound preset to a “Custom” label.



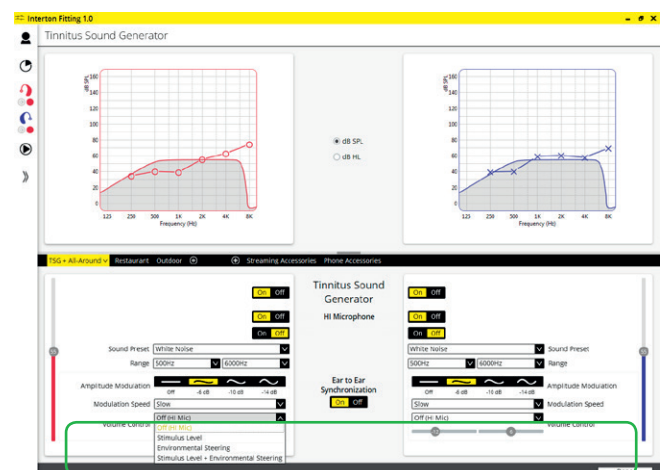
4. Customize the TSG features according to patient's preference

- "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 between fluctuations.
- Turn Synchronization "On" to enable ear-to-ear communication. Then any change to TSG features in one hearing instrument, automatically repeats in the other.



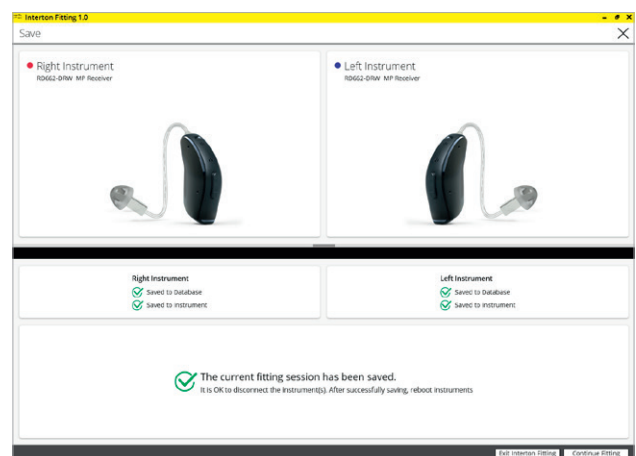
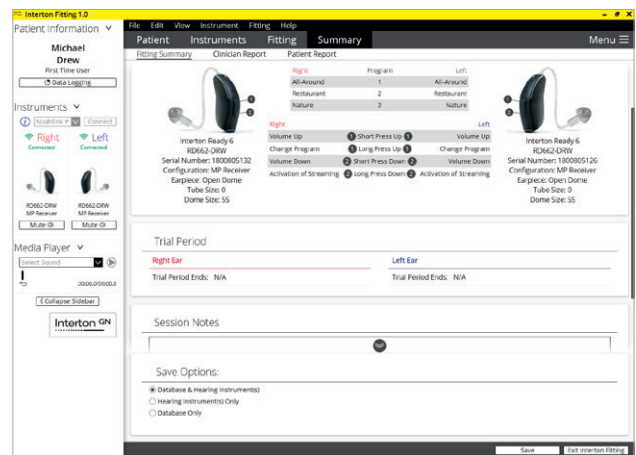
5. Customize the Volume Control options

- 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 "Environmental" allows the volume of the sound generator to automatically adapt to the listening environment, ensuring comfort in all situations.
- Selecting "Stimulus Level + Environment" will combine the use of these two features. It also allows manual volume adjustments while the Environment features are active.



6. Program and save

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



Using the Tinnitus Sound Generator with Interton Sound app

This section provides guidance on the functions available to your patients in Interton Sound app.

When you enable TSG in your patient's Interton hearing instrument(s) 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 instrument(s). Tinnitus Manager is only available in supported hearing instrument(s).

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

What your patient has access to in Interton Sound app

White noise controls

Sound variation:

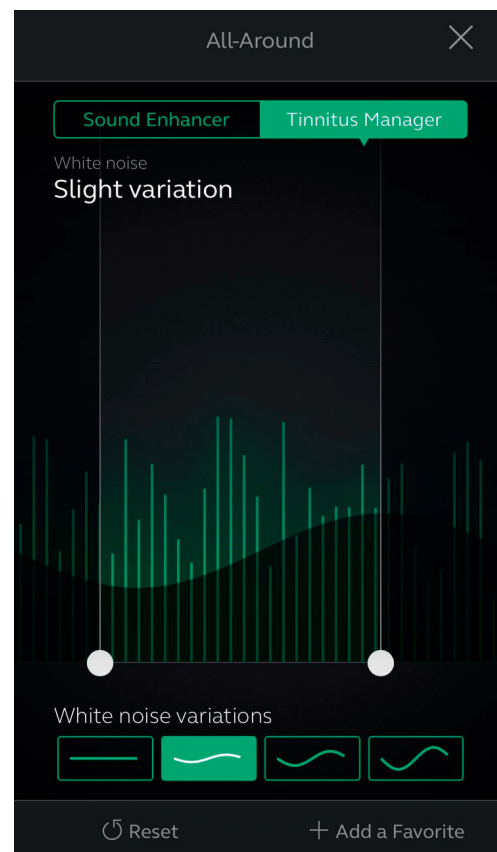
Adjust the variation of the white noise sound input by tapping one of the four buttons towards the bottom.

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

Adjust the *frequency shaping (Pitch)* 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, Off



Precautions and Warnings

General Precautions

- This Interton Fitting 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 amplification level prescribed. This change will be audible to the patient when the instruments 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 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 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 Sound Generator

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

General Warnings

- When connected, the Interton Fitting fitting software controls the acoustic amplification

levels in a hearing instrument. In some acoustic environments, over amplification can cause discomfort and damage to the patients 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 instrument. 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 patients comfort level, but it needs to be determined if it can obtain hazardous risk levels.
- The Fitting System initiates feedback calibration to measure the receiver to microphone transfer function. This is used primarily by the hearing instrument 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 System could show that the hearing instrument 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 DynaFit algorithm to interpret audio gram 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 Fitting Software.
- The Fitting System 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 instrument 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’s 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 practitioners: Special care should be exercised in selecting and fitting hearing instrument(s) 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 instrument user.
- Warning to hearing care practitioners: Special care should be exercised in selecting and fitting hearing instrument(s) 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 instrument that includes the Tinnitus Sound Generator feature. In accordance with NIOSH recommendations the user should not use the sound generator for more than eight (8) hours a day when this is set to a level of 85db SPL or above. When the sound generator is set to levels of 90db SPL or above the user 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 users will require guardian supervision while wearing the device.

Tinnitus Sound Generator

Warning to hearing healthcare professionals. Special care should be exercised in selecting and fitting hearing instrument(s) 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 user should not use the sound generator for more than eight (8) hours a day when this is set to a level of 85db SPL or above. When the sound generator is set to levels of 90db SPL or above the user 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 users will require guardian supervision while wearing the device.

A hearing healthcare professional should advise a prospective sound generator user 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 user that the prospective user has any of the following conditions:

- 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. Audiometric air-bone gap equal to or greater than 15dB at 500 hertz (Hz), 1000 Hz, and 2000 Hz.
 - g. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
 - h. Pain or discomfort in the ear.
- To prevent unintended usage by pediatric or physically or mentally challenged users, the volume control must be configured to only provide a decrease of the sound generator output level.

Manufacturer according to EU Medical Device
Directive 93/42/EEC:

Worldwide Headquarters

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CVR no. 55082715



WARNING points out a situation that could lead to serious injuries.
CAUTION indicates a situation that could lead to minor and moderate injuries.



Any issues relating to the EU Medical Device Directive 93/42/EEC should be
directed to Interton A/S.