Instructions for use

Genie 2 and Genie

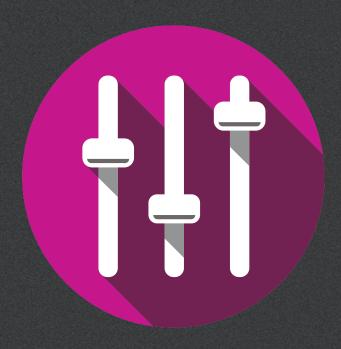




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The instructions for use is valid for Genie 2 | 2019.1 and Genie | 2017.1.

Genie 2 is a fitting software used for the Oticon Opn, Oticon Opn S, Oticon Opn Play, and Oticon Siya hearing aid families and models.

Genie is a fitting software used for all other Oticon hearing aid families and models.

A printed version of the IFU can be obtained through your local distributor.

Intended use

The fitting software is intended for fitting and updating of hearing solutions.

The fitting software can facilitate access to real-ear measurement equipment.

Intended use of Tinnitus SoundSupport

Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief for patients suffering from tinnitus as part of a tinnitus management program.

Tinnitus SoundSupport is not intended for clients below 18 years of age.

Tinnitus SoundSupport is targeted to licensed hearing care professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing loss. Fitting of Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.

Use environment

Used by hearing care professionals in a clinical setting.

Getting ready

Installation

Installation of the software will install both Genie 2 & Genie. If you already have a previous version of Genie 2 and/or Genie installed, it will automatically be updated and client sessions will be visible in both Genie 2 and Genie.

The installation program will start automatically when you insert the Genie 2 DVD/USB in the drive/port. Otherwise open Windows Explorer, browse to the drive and double-click "Setup.exe".

Follow the instructions on the screen.

System requirements

The system requirements to install and use Genie 2 & Genie are listed below:

Hardware requirements

- CPU: Intel Core i5, 4 cores, 2 GHz or faster
- 4 GB RAM or higher
- 8 GB free space on the hard disk
- Screen resolution: minimum 1280 x 1024 pixels
- DVD drive for DVD installation
- USB 2.0 port for USB installation and programming devices
- Keyboard and mouse
- Stereo or 5.1 surround sound card (recommended)

Operating System requirements

- Windows 7 SP1 (32/64 bit)
- Windows 8 (all editions except RT)
- Windows 10 (32/64 bit)

Optional tools

- NOAH 4 (if not running Genie 2 or Genie stand-alone)*
- A browser for access to Oticon web pages
- A PDF reader to read PDF documents
- We recommend that you protect your system by installing anti-virus protection software

Stand-alone Genie 2 or Genie and Database

When Genie 2 or Genie is running without NOAH, i.e. in stand-alone mode, a Client module is automatically installed. An additional Client organiser step will appear.

In the Client module, you can enter demographic data, such as client name, date of birth, address and the audiogram. Client data is automatically saved in the Genie 2 or Genie database and used for the subsequent fittings.

To start Genie 2 or Genie in stand-alone mode, click the Windows Start button, Programs, Oticon folder, and then Genie 2 or Genie.

* Do not install Genie 2 or Genie on a NOAH 2 or 3 system. Your Oticon fitting data in the NOAH 2 or 3 database will then no longer be accessible.

This is an overview of the functionality, main features, and tools in Genie 2. You can use it to learn about the typical steps and tools used for fitting in Genie 2.

| Genie 2 Organiser Steps - horizontal navigation



- 1. Client: Appears only when running Genie 2 outside NOAH
- Councelling: Appears only if Oticon Counselling Tools have been installed
- 3. Family: Choose Simulate or Connect

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- 4. Selection: Selection of hearing aid style and features
- 5. Fitting: Verification and fine-tuning of gain and settings
- 6. End Fitting: Verify and set client operations buttons, indicators and accessories. Save and Exit

The Task Pane - vertical navigation

In each organiser step there is a task pane on the left side of the screen. The task pane gives you access to tools and links which are related to where you are in the fitting process.



| Family step

Once you have chosen your client in NOAH or under Client in the Genie 2 stand-alone software, you will enter the Family step. From there choose one of the following options.



1. Connect hearing aids:

Open and close battery doors of hearing aids for detection with FittingLINK 3.0 or Noahlink Wireless and click the Connect button, or attach hearing aids with cables and click the Connect button. In follow-up sessions you can choose to proceed with instrument settings, do a new fitting, or transfer settings when connecting different hearing aids.

2. Simulate Connection:

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Click the Simulate button to simulate connection of hearing aids.

Transfer Settings in Genie 2

This tool allows transfer of settings (MPO, manual Adaptation manager, Soft sound perception, Brightness perception and local controls and indicators, as applicable) from a fitting session to a new selection of hearing aids. The tool automatically starts when new hearing aids, that differ from the present session, is connected or selected or it is opened from the Tools menu.

Please refer to help files for details on how to use Transfer Settings.

| Selection step

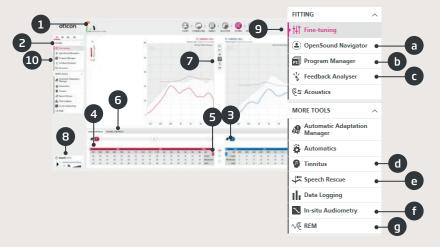
In this step, you specify your choices further by selecting the options shown below.



- Status field: View of selected style, power level, and acoustics as well as connection status
- 2. Tools in Task Pane (optional) e.g.
 - Personalisation: Customise the fitting for your client's specific listening needs. Oticon recommends to use it on the first fitting session
 - b. Acoustics: Select acoustic coupling to the ear, e.g. ear piece, tubing, and vent
 - Audiometric Data: Verify and update audiometric parameters to ensure correct gain prescription. This is especially relevant for the fitting of hearing aids for infants and young children
- 3. Selection of hearing aid family
- 4. Selection of hearing aid style
- 5. Selection of power level of receiver

| Fitting step

Gain and OpenSound Navigator™ defaults are based on the answers provided under Personalisation but they can be changed or verified in the Fitting step. If gain adjustments are required, consider using the Adaptation Manager before fine-tuning individual frequency bands.



- 1. Connection Bar: Connection status of the hearing aids
 - Grey: Not connected

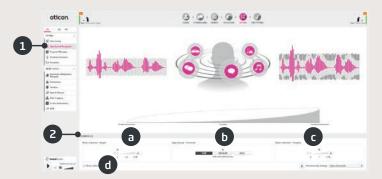
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- Green: Connected and settings are programmed and saved in hearing aids
- 2. Select active program and link programs to P1
- 3. Set the Adaptation Manager. A three step transition to prescribed gain
- 4. The arrow expands the number of fitting bands
- 5. The arrow gives access to MPO controls

- 6. Sound Controls:
 - Brightness Perception trimmer: Changes brightness of sound (for the VAC+ prescriptive rationale only)
 - Soft Sound Perception trimmer: Changes audibility of soft sound (for VAC+ prescpritive rationale only)
- 7. Graphs and graph views:
 - Curve type
 - Signal type
 - Input levels
 - Target view
 - Predicted feedback margin
 - Compression ratios
- 8. Oticon SoundStudio: Demonstration of various sound environments to help ensure that the client is fitted successfully
- 9. Paediatric Panel: Only available in paediatric fitting mode, which is enabled for children younger than 18 years
- 10. Tools in Task Pane (optional) e.g.
 - a. OpenSound Navigator™: Adjust how Oticon Opn, Oticon
 Opn S and Oticon Opn Play hearing aids perform in simple to
 complex listening environments (see separate section)
 Support in Noise: Adjust noise reduction and directionality
 in Oticon Siya hearing aids
 - b. Program Manager: Add and name programs, activate Auto Phone program and select prescriptive rationale
 - Feedback Analyser: Analyse the feedback risk (see separate section)
 - d. Tinnitus: Enable and adjust Tinnitus SoundSupport™ (see separate section)
 - e. Speech Rescue™ LX: Enable and adjusts frequency lowering
 - f. In-situ Audiometry: Measure the client's hearing by using the hearing aids as transducers (see separate section)
 - g. REM: Run REM AutoFit or set the hearing aids to measurement mode for use with your real-ear measurement equipment

| OpenSound Navigator™ Tool

This tool can verify or change the prescribed settings for your client. Prescribed settings are marked with a **b**. The tool is specifically used to adjust how the client's hearing aids perform in simple and complex environments.



- OpenSound Navigator™ response: Graphical view of changes made in YouMatic™ LX below, pertaining to directionality and noise reduction settings in simple to complex environments
- 2. YouMatic LX:
 - a. Noise Reduction Simple: Noise reduction settings for simple listening environments
 - b. Open Sound Transition: Adjust the amount of help (Low, Medium, High or Very High) your client needs in order to focus on speech in noisy environments. The Transition Bar right above it reflects your choices graphically by showing you at what point help will kick in for your client. Alternatively, you can choose a non-adaptive directionality, Pinna Omni, or the Full Directionality option in the lower right corner
 - c. Noise Reduction Complex: Noise reduction settings for complex environments
 - d. Noise Reduction: Deactivate noise reduction

| Feedback Analyser Tool

Feedback analysis is recommended for new fittings and whenever fitting parameters change.



- 1. Start: Run a feedback analysis with the selected hearing aid and acoustic coupling to the ear
- 2. Clear: Delete the analysed feedback margin

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3. Background Noise Level: Indicates noise level in room and allows you to monitor when the environment is too loud for valid feedback analysis

I Tinnitus



- Tinnitus SoundSupport on/off: Activate or deactivate Tinnitus SoundSupport
- 2. Binaural linking: Default is off
- Tinnitus relief sound selection: Four Broadband Sounds and three Nature Sounds. Default is "Shaped" (to audiogram)
- 4. Signal Level: Adjust one or both ears. Initial level is based on the client's audiogram
- 5. Modulation: Broadband sounds can be personalised by adding one of four modulation types: Tranquil, Mild, Spirited, and Bustling
- Trimmer table: Broadband Sounds can be shaped in 16 frequency bands
- 7. Automatic Level Steering: On/off option. Automatically lowers tinnitus relief sounds when environmental sounds become louder
- 8. Microphone Hearing Instrument: On/off option to turn hearing aid microphone off
- Max wearing: A Max wearing time indicator will appear if tinnitus relief sound levels exceed a level that could lead to permanent hearing damage and exposure should therefore be limited

In-situ Audiometry Tool

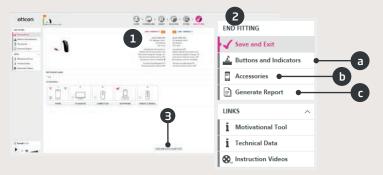
In-situ Audiometry lets you measure the client's hearing using the hearing aids as transducers. This means that the results will be specific for the instrument and acoustic coupling.



- 1. Tone type
- 2. Talk over
- 3. Play tone
- 4. Audiogram use

| End Fitting step

The End Fitting step is the final step in the fitting process. Here you can verify correct programs, rationales and settings. The following end-of-fitting functions are also available.



- 1. Overview of final hearing aid settings and functionality
- 2. Use End Fitting Task Pane to
 - a. Define Buttons and Indicators: Button operation, volume control, beep setting and LED patterns
 - Manage Accessories: Volume level and balance of paired: smartphone, ConnectClip and TV adapter. Also manage autophone and DAI/FM programs
 - c. Generate Reports: Print, save or send by email a selection of reports according to your needs and your client's needs
 - d. Rechargeable Batteries: Only available when connected to miniRITE R. Shows current battery level, battery health and instruction on how to replace the battery
- Save And Exit/Save And Go To Client Step: Saves and programs final settings and adjustments into your client's hearing aids.
 Settings and adjustments have also been saved continuously throughout the fitting so it is always safe to disconnect the hearing aids without losing important data

Oticon RemoteCare

Oticon RemoteCare enables you to communicate with your client and to make real-time adjustments to your client's hearing aids remotely. If you cannot upload your changes remotely, a physical visit is necessary. See Genie 2 help file for fitting tools that are not available with Oticon RemoteCare.

Additional system requirements

- PC camera OR external camera
- Microphone and speakers OR headset
- Email account
- A stable Internet connection: recommended minimum speed 1/1 Mbit/s (check with your provider)

Client system requirements

Oticon Opn (FW6.0), Oticon Opn S, Oticon Opn Play, or Oticon Siya hearing aids - paired to your iPhone

- An iPhone. See compatible models here: www.oticon.global/ hearing-aid-users/support/faq/compatibility
- Updated iPhone software: iOS 11.0 or later. (To find out what iOS version you have go to: Settings, General, About, Version)
- A stable Internet connection: recommended minimum speed 1/1 Mbit/s (check with your provider)
- An e-mail account
- An Apple-id account

IMPORTANT NOTICE

The hearing care professional is responsible to obtain the license needed to use Oticon RemoteCare with the clients. Oticon does not take any responsibility.

| Enable Oticon RemoteCare

Create account

Open the Oticon RemoteCare invitation email sent by your local representative and follow the instructions.

Enable Oticon RemoteCare in Genie 2

Go to Preferences, Edit preferences, Customise Software section, RemoteCare tab. Select 'Turn on RemoteCare'.

Oticon RemoteCare fitting



1. Toggle to turn on RemoteCare

2. Log in

3. Enter client account details and press 'Continue'

Click Start an appointment to
 establish communication with client

REMOTEGATE

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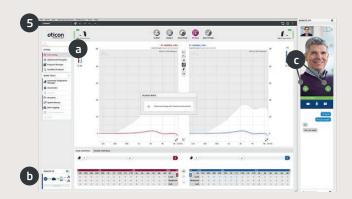
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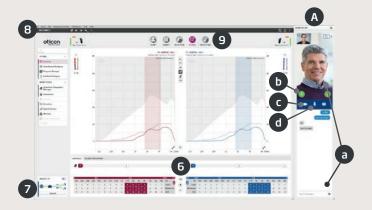
Note: It is only possible to start an appointment when the client is already present/has started an appointment



Click 'Connect' to detect and connect to the client's hearing aid(s).
 The status indicators turn green when the hearing aids are connected

The connection status of the hearing aids is indicated three places:

- a) Connection Bar
- b) RemoteCare connection overview
- c) RemoteCare communicator



RemoteCare communicator (A)

- a) Enables text messaging and communication via audio and video between you and your client
- b) Hearing aid status indicators
- c) Enable/disable your camera
- d) Mute/unmute your microphone
- 6. Fit hearing aids as you would do normally, if needed
- 7. Click 'Upload' to upload the new settings to the hearing aid(s)
- 8. Click 'Disconnect'. The hearing aid(s) will be disconnected from Genie 2 and will restart

Note: You can also disconnect the hearing aids from the End Fitting screen

9. Go to the End Fitting step and click 'Save and exit'/'Save and go to client step' to save and end the session with the client

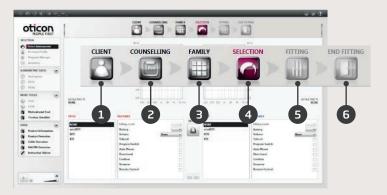
This is an overview of the functionality and main features and tools in Genie. You can use it to learn about the typical steps and tools used for fitting in Genie.

| Family step



- Attach hearing aid and click DETECT OR
- 2. To simulate, select a family button

The Organiser steps - horizontal navigation



- 1. Client: Appears only when running Genie outside NOAH
- 2. Counselling: Appears only if eCaps has been installed
- 3. Family: Selection of all hearing instrument families
- 4. Selection: Select instrument styles and features
- 5. Fitting: Verifying and fine tuning of settings
- 6. End Fitting: Verify and set client operations buttons. Save, Program and Exit

The Task Pane - Vertical navigation



In each Organiser step there is a Task Pane that gives access to tools and links related to where you are in the fitting process.

| Selection step



- 1. View style and prescribed vent in the status field
- 2. Optional tools in the Task Pane:
 - a. Personal Profile
 - b. Program Manager
 - c. Acoustics

| Fitting step

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Verify the prescribed setting, for example by using the various built-in sound environments. If adjustments are required, consider using the Adaptation Manager before adjusting individual controls.



- 1. The Connection Bar indicates whether the instrument is
 - Not connected (grey)
 - Connected (yellow)
 - Connected and settings are programmed and stored in the instruments (green)
- 2. Sets the Adaptation Manager. A three step transition to Prescribed gain
- 3. Sets the detail and comfort level of soft sounds
- 4. The arrow expands the number of controls
- 5. The arrow gives access to MPO controls
- 6. To program instruments during the fitting, press Program Instrument button
- 7. Select Active Program and link programs to P1
- 8. Tools in Task Pane (optional) e.g.
 - Automatics Manager (Automatics & YouMatic)
 - Program Manager (see below)
 - Feedback Manager
 - Speech Rescue[™] (frequency lowering available in Oticon Dynamo and Oticon Sensei SP hearing aids)
 - Tinnitus (See Tinnitus Fitting Guide)
 - Live Demonstration
 - Memory (and Life Learning)
 - Fitting Assistant (see below)

| Program Manager

Use this tool to add or change the content of programs



- 1. Add a new program
- 2. Select content of program
- 3. Activate Auto Phone

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- 4. Change the order of the programs
- 5. Select the program (P1, P2...) you want to change
- 6. Select Controls in the Task Pane to return to Fitting view

| Fitting Assistant

A fine-tuning tool to handle the most common client complaints.



- 1. Select a tab: General Perception, Speech Perception or Own Voice
- 2. Select a control and direction for the desired result (left or right the initial setting is in the middle)
- 3. Hold the cursor over the desired step and a tool tip will pop-up with a suggestion
- 4. Use the sound environment buttons to verify the adjustment
- 5. Select Controls in the Task Pane to return to Fitting view



- 1. Link Streamer to instruments:
 - Fitting Link: Click 'Read' serial' no. or enter Streamer serial number
 - NOAHlink: Click 'Read' serial no. or enter Streamer serial number
 - HI-PRO: Enter Streamer serial number
- 2. Use End Fitting Task Pane to;
 - a. Define button operation and activate VC function
 - b. Define Phone programs and activate Auto Phone options
 - c. Open and print customised User Instructions
- 3. Click Save, Program and Exit

A Warnings

You should familiarize yourself with the following general warnings and the entire contents of this booklet before using the fitting software to avoid possible client injury or hearing aid failure.

| General Safety Precautions

For safety reasons, always read the Intended Use of the fitting software, the risks related to the fitting level of the Tinnitus SoundSupport feature and the recommended wearing times.

Connection

Take care not to lose the wired or wireless connection to the hearing aid or let communication errors interrupt the fitting flow.

| Choking Hazards

For safety reasons, caution must be taken when fitting children younger than 36 months. Children younger than 36 months must always use a tamper-resistant battery drawer.

For safety reasons, always use ear moulds when fitting children younger than 36 months.

| Firmware

For safety reasons, always ensure that the client is not wearing the hearing aid during a firmware update, as the updated hearing aid will be reset to factory settings after the update. Moreover, do not give the hearing aid to the client before restoring user settings.

Ensure that the serial number of the connected hearing aid corresponds to the serial number registered in the office automation system for the relevant client.

Always note the firmware version of the hearing aid before and after a firmware update.

Ensure that the firmware version of the programming device is compatible with the firmware version of the fitting software.

Avoid interruptions or connection failure to the hearing aid or connectivity device during a firmware update.

I REM System

Pay attention to any error messages from the REM system caused by incorrect or unintended data sent to the REM system.

| Tinnitus

For safety reasons, always caution the client about limiting the use of the Tinnitus SoundSupport feature to ensure safe listening levels.

Be aware of the high sound-pressure level generated by the Tinnitus SoundSupport feature.

Note the recommended limits to the wearing time of the Tinnitus SoundSupport feature as shown in the fitting software. In the print report and the Instruction for Use for the hearing aid, always enter the maximum wearing time per day.

Tinnitus SoundSupport is not intended for clients below 18 years of age.

Definition of product symbols

Power Instruments

For safety reason, caution should be taken when selecting, fitting and using a hearing aid where the maximum sound pressure capability exceeds 132 dB SPL (IEC 711) as there may be a risk of damaging residual hearing of the hearing aid client.

| Transfer Settings

Your client must not wear the instruments while transferring settings.

In-situ Audiometry

In-situ Audiometry should not be used for diagnostic purposes. Make sure that you add an audiogram in NOAH or the Client step in Genie 2 before you conduct In-situ Audiometry.

Remove any REM AutoFit results before you conduct In-situ Audiometry.

Make sure you carry out In-situ Audiometry in a quiet area.

Tone Burst ABR

Please enter ABR values as eHL, this ensures the correct prescription gain is applied to the audiogram.

Disclaimer

The manufacturer does not take responsibility for the consequences of using this fitting software outside intended use or warnings.

The following are definitions for symbols that may appear in the instructions for use for Genie and Genie 2:

Symbol	Description
\triangle	Warnings Text marked with a warning symbol must be read before using the product.
	Manufacturer The device is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
C E ₀₅₄₃	CE mark The device complies with Medical Device Directive 93/42/EEC. The four digits number indicates the identification of the notified body.
	Electronic waste (WEEE) Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/ EU on waste and electrical equipment (WEEE).
USB	Consult electronic instructions for use Indicates the need for the user to consult an electronic instructions for use.
i	Consult instructions for use Indicates the need for the user to consult an instructions for use.



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