Instructions for use

Genie
2017.1

oticon
life-changing **technology**
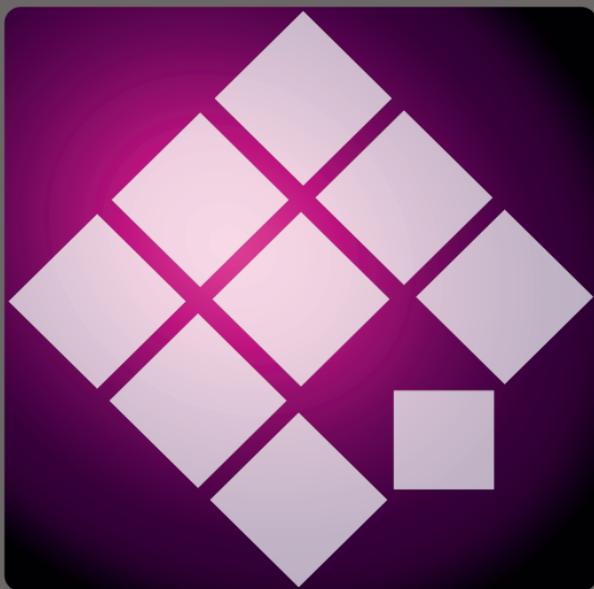
Introduction

The following instructions for use are valid for Oticon Genie 2017.1.

Genie is a fitting software used for all legacy Oticon hearing instrument families and models. For example, Oticon Alta2, Oticon Nera2, Oticon Ria2, and all previous families.

A printed version of this instruction for use can be obtained through your local distributor.

For your convenience, this booklet contains a navigation bar to help you easily navigate through the different sections.

Intended use

The fitting software is intended for fitting of hearing solutions. The fitting software can facilitate access to real-ear measurement equipment.

User environment
Used by hearing care professionals in a clinical setting.

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 users below 18 years of age.

Tinnitus SoundSupport is targeted to licensed hearing care professionals (audiologists, hearing instrument 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.

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Installation

The Genie fitting software installation is provided in a DVD/USB drive that contains the installation file.

The installation program starts automatically when you insert the Genie DVD/USB in the drive/port. Otherwise open Windows Explorer, browse to the relevant drive and double-click the **Setup.exe** file.

When you run the installer, follow the installation instructions on the screen.

If you already have a previous version of Genie installed, it will be updated automatically, and user/client sessions will still be visible.

System requirements
The following are the minimum system requirements to install and use Genie:

Hardware requirements
- CPU: Intel Core i5, 4 cores, 2 GHz or faster
- 4 GB RAM or more
- 8 GB free hard disk space
- 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), all editions.
- Windows 8 (32/64 bit), all editions except RT.
- Windows 10 (32/64 bit), all editions except ARM platform and Windows 10 S.

Optional tools
- NOAH 4 audiology software
- An internet browser to access the Oticon website
- Adobe™ Acrobat Reader™ software
- It is recommended that you protect your system by installing anti-virus protection software

Stand-alone Genie database
When you run Genie without the NOAH audiology software, or in stand-alone mode, a Client module is automatically installed, and an additional **Client** step appears.

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

To start Genie in stand-alone mode, click the **Windows Start** button, navigate to the Genie folder and click the Genie application.

Do not install Genie on a system running NOAH 2 or 3. If you do, the Oticon fitting data in the NOAH 2 or 3 database is no longer accessible.

Genie overview

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

The procedures contained in this booklet help you with the most essential steps, such as connecting the instrument, performing a fitting and saving your changes, but they are not an exhaustive list.

If you need more detailed information about any of the features in Genie, refer to the built-in help guide.

To access it, run Genie, then go to the Help menu, and then click **Help on Genie**.

The Organiser steps – horizontal navigation
The organiser, which is divided into six parts, helps you navigate through the entire fitting process by structuring the fitting flow in a series of steps. The following list describes the steps.

- **Client:** This button appears only when you run Genie without NOAH or in stand-alone mode. In this step you can enter a hearing instrument user's demographic data, such as name, date of birth, address and the audiogram, among others. You can also add, edit, search or delete users.
- **Counselling:** This button appears only if eCaps / counselling software has been installed.
- **Family:** This step lets you select a hearing instrument from all hearing instrument families.

- **Selection:** This step lets you select instrument styles and features to personalise the fitting.
- **Fitting:** This step lets you verify, adjust and fine-tune the settings of instruments. The functions in this step reflect the different fitting modes available in Genie.
- **End Fitting:** This step lets you verify and set individual user operational settings for buttons, indicators and accessories, in order to finalise the fitting session with the user. You can save the settings, as well as session information on the database and hearing instruments and exit Genie.

The Task Pane – vertical navigation
In each organiser step there is a task pane, located on the left-hand side of the screen. The task pane gives you access to tools and links that are relevant to where you are in the fitting process.

Family step

The Select Family screen is the initial step or entry screen when working with Genie. In this step, you can either have Genie detect instruments or you can manually select instruments (simulate).

Simulate helps you check possible configurations of a hearing instrument, or to see how tools look and work.

To detect and connect hearing instruments in Genie
- To detect and connect hearing instruments and connect them to your computer, in the **Family** step, click the **Detect** ⚒ button.
  - If you run Genie without NOAH, or in stand-alone mode, you are first taken to the **Client** step. Ensure you either add the user or double-click the existing user from the list. You are then taken to the **Family** step.

To simulate an instrument being connected to Genie
- In the **Family** step, hover the mouse over the icon representing the family of the instrument, for example, Alta2, and click the instrument you would like to simulate.

  You are then taken to the **Selection** step, where you can manually choose the instrument(s) you would like to simulate, as well as its style and features.

Selection step

In the **Selection** step you can select hearing instrument's styles and features. This step also includes the **Connection status** section, which shows you a photo of the style and vent of the selected instrument.

The Select instruments screen is the entry screen for the **Selection** step and it's where you can detect or manually select (simulate) an instrument.

If a non-custom instrument is detected or simulated, the instrument's features are preselected to match the instrument style.

Be aware that certain instruments allow you to change the fitting level.

In the **Selection** step, and after you select or detect the instrument, in the **Connection status** section, the color of the Connection Bar indicates whether the instrument is:

- Not connected – Grey.

- Connected – Yellow.

- Connected and settings are programmed and stored in the instrument – Green.

- Fitting data is being stored in the instrument – Green (and flashing).

Tools

The following are the optional tools in the Task pane.

- **Personal Profile**
  This tool can help you achieve a more personalised initial fit by adding user information such as age and gender among other parameters. The user can also answer personal prescription questions to further personalise the fit.

- **Program Manager**
  This tool lets you add, change and delete programs. You can have up to four programs configured in an instrument. Normally, this is used as part of the initial settings when fitting a hearing instrument, and you can modify the program template, prescriptive rationale and personal profile of the user.

- **Acoustics**
  Relevant for BTE and RITE styles. When the selected vent or dome, hook or tube match those in the physical instrument, you can achieve a better initial fit. In a custom instrument, Genie automatically reads the vent.

- **Audiometric Data**
  It consists of three tools, Audiogram, Real Ear to Coupler Difference (RECD) and Real Ear Unaided Gain (REUG), and helps you verify and update audiometric parameters to ensure correct gain prescription. This is mainly relevant when fitting hearing instruments for infants and children.

  - **Audiogram**
    Displays the hearing threshold level and test signal transducer. Genie automatically reads audiogram data from NOAH.

  - **RECD (Real Ear to Coupler Difference)**
    The RECD tool is useful when fitting children and users who are difficult to test. You can select predicted data, REM or EasyRECD™. Predicted data offers standard RECD values depending on the user's age and the used fitting rationale. REM uses user-specific RECD calculated by external diagnostic modules. EasyRECD™ is available only for paediatric and Super Power instruments. The user-specific EasyRECD™ values are measured and calculated by Genie.

  - **REUG (Real Ear Unaided Gain)**
    The REUG tool is useful when fitting adults with abnormalities in the ear canal or middle ear. You can select predicted data or REM. Predicted offers standard REUG values depending on the user's age. REM uses user-specific REUG calculated by external diagnostic modules.

Fitting step
In this step, in the Controls entry screen, you can fine-tune the gain and use a broad range of fitting tools to adjust and demonstrate the instrument, as well as verify the prescribed settings.

If you have to adjust gain, and before you adjust individual controls, consider using the **Adaptation Manager** prior to fine-tuning individual frequency bands.

Tools
The following are the optional tools in the Task pane.

- **Automatics Manager (Automatics & YouMatic)**
  Lets you change the personal profiles in YouMatic manager or configure automatic features.

- **Program Manager**
  The Program Manager tool lets you add, change and delete programs. You can have up to four programs configured in a hearing instrument. Normally, this is used as part of the initial settings when fitting a hearing instrument, and you can modify the program template, prescriptive rationale and personal profile of the user.

- **Feedback Manager**
  This tool lets you analyse the feedback path and applies feedback limits to the instruments.

- **Speech Rescue™**
  It is a frequency lowering tool that helps you improve speech understanding for users with severe high-frequency hearing loss. (Frequency lowering is only available in Super Power instruments, for example Oticon Dynamo and Oticon Sensei SP).

- **Tinnitus**
  Enable and adjust Tinnitus SoundSupport (Read the **Tinnitus SoundSupport** section in this booklet).

- **Live Demonstration**
  This tool shows in real-time how the instrument evaluates the listening environment.

- **Memory (and Life Learning)**
  Memory shows you how the instrument has been used, and to which environments it has been exposed to, due to the instrument's ability to learn from the collected data.

  Life learning ensures that the overall volume control (VC) setting matches the preferred VC setting in various environments. It learns how the instrument is used and adjusts settings accordingly.

- **Fitting Assistant**
  (Read the **Fitting Assistant** section in this booklet).

- **In-situ Audiometry**
  With this tool you can measure the user's hearing by using the hearing instruments as transducers (Read the **In-situ Audiometry** section in this booklet).

- **REM**
  The REM tool (which contains REM Autofit) lets you set the hearing instruments in measurement mode for use with your Real Ear Measurement equipment.

In-situ Audiometry tool

The In-situ Audiometry tool lets you find the user's hearing thresholds using the hearing instruments as transducers. This means the fitting can be fine-tuned to be specific for the ear, the instrument and the acoustic coupling.

Ensure that the user's instrument is detected and connected in Genie before you open the In-situ Audiometry tool.

To open the in-situ Audiometry tool
- In the **Fitting** step, in the task pane, in the **More Tools** section, click **In-situ Audiometry**.

  Tone controls – To change the level and frequency presented

1. In the in-Situ Audiometry tool, in the audiogram graph, the conventional audiogram is represented as a gray curve. With your keyboard, press the **up** or **down** arrow keys to increase or decrease the level of the signal that is presented.

   Alternatively, with your mouse, turn the scrolling wheel to increase or decrease the level of the signal.

2. With your keyboard, press the **right** or **left** arrow keys to switch between frequencies. Alternatively, with your mouse, click the graph to select frequency, and turn the scrolling wheel accordingly.

3. To change the tone type, in the bottom left pane, in the **Audiometry Method** section, select **Continuous tone** or **Pulsed tone**.

Talk over – To communicate with the user or give instructions during the Audiometry
- To activate Talk over, in the In-situ Audiometry tool, in the center of the screen, click the Talk over icon. ♪ Click the button again to deactivate it.

  ○ While Talk over is active, the volume slider located under the icon helps you adjust the volume of the instrument.

Audiogram use – To choose the type of audiogram
- To change the type of Audiogram used, in the bottom right pane, select **Use normal audiogram** or **Use in-situ audiogram for the measured side(s)**.

Tinnitus SoundSupport

The Tinnitus SoundSupport feature is a tool that generates sounds for use in a Tinnitus management program, to help users suffering from Tinnitus.

You can select and modify sounds to suit the user's preference. Also, the tool is available in all programs except Phone and Telecoil.

To activate or deactivate Tinnitus SoundSupport
1. In the **Fitting** step, on the Task pane, under the **More tools** group, click **Tinnitus**.

2. In the bottom pane, on the right-hand side of the screen, click the **ON** or **OFF** button to activate or deactivate Tinnitus SoundSupport respectively.

   Ensure that the hearing instrument is connected and that it supports Tinnitus SoundSupport. If you do not see the Tinnitus option in the Task pane, it is possible the instrument does not support it.

Fitting Assistant

The Fitting Assistant is a tool in the **Fitting** step that lets you fine-tune the hearing instrument and handle the most common user requests. This tool can be effective in helping you fix or correct any issue that the user may have with the sound at the fitting or at a follow-up visit.

The tool can be used individually for each program in the hearing instrument.

In the Fitting Assistant, you can change the settings for **General Perception**, **Speech Perception** as well as **Own Voice**.

To fine-tune the hearing instrument
1. In the Fitting Assistant screen, in the bottom pane, click the **General Perception**, **Speech Perception** or **Own Voice** tab.

2. Click the red or blue coloured bars to the relevant direction (left or right) to adjust the level of loudness, sound quality, distant sounds, and others.

3. In the bottom pane, and according to the settings you want to adjust, you can find the sound environment buttons that play sounds that are relevant to the selected setting.

   This allows for the hearing care professional to verify the adjustments made, and for the user to evaluate the changes in a real-life environment. To do this, click one of the buttons, for example, **Couple at Home, Traffic, Cutlery** or **Footsteps on floor**.

   Each tab has different settings and built-in sounds you can adjust, to help the user evaluate the setting. The initial or default setting is in the middle of the control.

   If you hold the cursor over the desired setting, a tooltip appears and shows you how the changes will affect the low, middle and/or high frequencies.

End Fitting step

The **End Fitting** step is the final step in the fitting process. It lets you verify correct programs, rationales and settings, as well as see an overview of the final hearing instrument settings and functionalities.

This step helps you connect the accessories to instruments, see all the information about the current fitting, complete your programming of the instrument, as well as save the settings and exit Genie.

To save settings and end fitting session
- In the **End Fitting** step, click the **Save, Program and Exit** button.

  o Alternatively, to return to the **Client** step, click the **Go to Client** button.

  In both options you will be prompted to save your data in the instrument and/or in the standalone database. Clear or select the relevant checkboxes and when you are finished, click **OK**.

Tools

The following are the optional tools in the Task pane.

- **Buttons and Indicators**
  This tool helps you define button operation, beep setting, and activate the volume control function, among others.

- **ConnectLine**
  A fine-tuning tool for ConnectLine solutions that lets you change the configuration of the Streamer Pro, and if necessary, it offers to update the Streamer firmware.

- **Phone and DAI/FM**
  This tool helps you define phone programs and activate Autophone options.

⚠ Warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your fitting software.

Contact your local distributor if you experience unexpected operations or serious incidents with the fitting software during use or because of its use. Serious incidents should also be reported to the national authorities.

General safety precautions
It is important that you read the **Intended Use** of the fitting software in the **Introduction** section of this booklet, the risks related to the fitting level of the Tinnitus SoundSupport feature, and the recommended wearing times.

Connection
It is important that you do not lose the wired or wireless connection to the hearing instrument 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 moulds when fitting children younger than 36 months.

Firmware
During a firmware update, ensure that the user is not wearing the hearing instrument(s) due to the updated instrument being reset to factory settings after the update.

Moreover, do not give the instrument back to the user before restoring user settings, and ensure that the serial number of the connected instrument corresponds to the serial number registered in the office automation system for the relevant user.

It is also important that you are aware of the firmware version of the hearing instrument before and after an update, and 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.

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 user about limiting the use of 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 users below 18 years of age.

Power instrument
Special care should be exercised in selecting, fitting and using a hearing aid where maximum sound pressure capability exceeds 132 dB SPL (IEC 6038-4) as there may be a risk of impairing the remaining hearing of the hearing instrument user.

In-situ Audiometry
Do not use In-situ Audiometry for diagnostic purposes.

Also, before you conduct the In-Situ audiometry, ensure that you add an audiogram in NOAH or the **Client** step in Genie.

Before you conduct In-situ Audiometry, ensure you remove any REM AutoFit results, and carry out the Audiometry in a quiet area.

Tone Burst ABR in Genie 2017.1
In Genie 2017.1, in the audiogram, ensure that you enter ABR values as eHL. This ensures the correct prescription gain is applied based on the audiogram.

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

Technical information

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Waste from electronic equipment must be handled according to local regulations.

	Description of symbols used in this booklet
⚠	**Warnings** Text marked with a warning symbol must be read before using the device.
🏭	**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.
CE 0543	**CE mark** The device complies with Medical Device Directive 93/42/EEC. The four digit 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).

	Description of additional symbols used on labels
REF	**Catalogue number** Indicates the manufacturer's catalogue number so that the medical device can be identified.
📖 eIFU indicator	**Consult electronic instructions for use** Indicates the need for the user to consult electronic instructions for use.
📖	**Consult instructions for use** Indicates the need for the user to consult instructions for use.