Instructions for use

Genie 2 2020.1





Introduction

The following instructions for use are valid for Oticon Genie 2 2020.1.

Genie 2 is a fitting software used for Oticon Opn S™, Oticon Opn™, Oticon Xceed, Oticon Opn Play™, Oticon Xceed Play, Oticon Ruby, and Oticon Siya hearing instrument families.

A printed version of this booklet can be obtained through your local distributor.

| Start-up | Working in Genie 2 | Warnings | More info |

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

Intended use

Intended use	The fitting software is intended for fitting and updating of hearing solutions. The fitting software can facilitate access to real-ear measurement.
Indications for use	No indications for use.
Intended user	Hearing care professional.
User environment	Clinical setting.
Contraindications	No contraindications.
Clinical benefits	See clinical benefits of the hearing aid. If you have additional questions about the use of the fitting software, please contact your local distributor.

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 2 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 2 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 2 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 2:

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 2 database

When you run Genie 2 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 2 database and used for any subsequent fittings.

To start Genie 2 in stand-alone mode, click the **Windows Start** button, navigate to the Genie 2 folder and click the Genie 2 application.

Do not install Genie 2 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 2 overview

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.

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 2, refer to the built-in help guide.

To access it, run Genie 2, then go to the **Help** menu, and then click **Help on Genie 2**.

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 2 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 Oticon Counselling Tools have 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 2.
- 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 instrument and exit Genie 2.

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

After you select or add the user in NOAH or the Genie 2 stand-alone database, the next step in the fitting flow is the **Family** step.

This is the initial step or entry screen when working with Genie 2. You can either have Genie 2 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 2

- Restart the hearing instruments for detection with FittingLINK 3.0 or NOAHlink Wireless, and in the Family screen, click the Connect button, alternatively attach the hearing instruments with cables, and click the Connect button.
 - If you run Genie 2 without NOAH, or in standalone 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 2

In the Family step, in the bottom pane, click 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.

Transfer Settings in Genie 2

Genie 2 lets you transfer settings from a fitting session to a new selection of hearing instruments.

The Transfer Settings tool automatically starts when new hearing instruments that are different from the current session are connected or selected. You can also manually open the tool.

Before transferring the settings, Genie 2 will prompt you about which settings can or cannot be transferred.

To manually open the transfer settings option

• Go to the **Tools** menu, and then click **Transfer Settings**.

Selection step

In the **Selection** step you can select a 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's 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.

Tools

The following are the optional tools in the Task pane.

Personalisation

This tool helps you customise the fitting for a user's specific listening needs. It is recommended that you use it in the first fitting session or when the user's experience level changes.

Genie 2 asks about the user's typical listening situations, previous amplification experience, and ability to process sounds. Moreover, the tool has built-in sound demos that can help the user answer the questions.

Your selections in the **Personalisation** tool will only influence the prescription for instruments within the Premium category.

Acoustics

This tool helps you select acoustic coupling to the ear, for example, earpiece, tubing, and vent. Genie 2 applies gain according to the acoustical parameters.

This tool is also available in the **Fitting** step and the options displayed depend on the instrument style.

Audiometric Data

Audiometric Data 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

You can use this tool to specify the measurement method, the transducer and measurement unit used for the audiogram.

- RECD (Real Ear to Coupler Difference)
 The RECD tool is useful when fitting children and users who are difficult to test. When you perform a RECD measurement, the degree of cooperation and amount of time required from the user is greatly reduced compared to other REM measurements.
- REUG (Real Ear Unaided Gain)
 The REUG tool is useful when fitting adults with abnormalities in the ear canal or middle ear.

Fitting step

In this step, in the Controls entry screen, you can fine-tune the gain and use a broad range of fitting tools including classic gain trimmers, meta-trimmers, REM tool and Feedback Analyser.

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.

OpenSound Navigator™

This tool helps you adjust how Oticon hearing instruments process sound in simple to complex listening environments. OpenSound Navigator is only available for hearing instruments within the Premium category.

Support in Noise

You can adjust noise reduction and directionality in Oticon hearing instruments. Support in Noise is only available for instruments within the Essentials category.

• 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.

• Feedback Analyser

This tool lets you analyse the feedback path and apply feedback margins to the instruments.

Acoustics

Read the **Selection** step's **Tools** section for more information.

Tinnitus

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

• Speech Rescue™ LX

This tool helps you enable and adjust frequency lowering.

• 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.

Bimodal Fitting

This tool provides specific fine-tuning controls to help you adjust the instrument setting for users with a cochlear implant on one side, and an instrument on the other. This tool is only available in monaural fittings.

Oticon SoundStudio

A built-in 3D sound application that helps you demonstrate various sound environments to simulate real-life sounds and situations in your clinic.

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 2 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

- 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.

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. ⅓

Click the button again to deactivate it.

The Talk over icon is turned off by default. The amplification for Talk over is based on the conventional audiogram. If there is no audiogram, there will be no amplification.

Play tone - To play a tone in the hearing instrument

- In the middle pane, click the **Play Tone** button. The tone is played in the hearing instrument and continues as long as you hold the mouse key.
 - To change the tone type, in the bottom left pane, under Tone type, select Continuous or Pulsed.

Audiogram use - To choose the type of audiogram

 To change the type of Audiogram used, in the bottom right pane, under Audiogram use, select Use conventional 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 your 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 your instrument does not support it.

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's settings and functionalities.

This step also shows which accessories can be paired with the hearing instruments, which ones are already paired or delete the pairing altogether.

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 2.

To save settings and end fitting session

- 1. In the **End Fitting** step, click the **Save and Exit** button.
 - If you are running Genie 2 in stand-alone mode, click the Save and Go to Client Step button.

You are now presented with the options to save to the hearing instruments, in NOAH, or in the standalone database (without NOAH).

 To save to your hearing instrument(s): In the Save Settings dialog box, the checkboxes are selected by default. If you want to save, select the relevant checkbox, and if you want to discard all the changes since you last saved settings, clear both checkboxes.

Note

You cannot discard changes if there is a conflict between the hearing instrument settings and Genie 2 settings, and you have selected Genie 2 settings or if the instrument contains factory settings.

- 3. To save all current session information in NOAH or in the stand-alone database, in the Save Settings dialog box, select the in-standalone database checkbox. Clear the checkbox to discard all changes since you last saved.
 - Optionally, if you want to add a session comment, in the Save settings dialog box, in the Session comment field enter your comment or note. The comment appears in the NOAH and Genie 2 stand-alone session lists.
- 4. 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, volume control, beep setting and LED patterns.
- Accessories: You can manage accessories, for example you can set volume level and balance of the following: Smartphone, ConnectClip, TV Adapter, EduMic and Remote Control.
- **Generate Report:** Print, save or email a selection of reports according to your needs and the user's needs.
- Rechargeable Batteries: It shows current battery level, battery health and instructions on how to replace the battery.

Oticon RemoteCare™

Oticon RemoteCare enables you to communicate with the user and make real-time adjustments to a user's hearing instrument(s) remotely. If you cannot upload your changes remotely, a physical visit is necessary.

For more information regarding the fitting tools that are not available with Oticon RemoteCare, read the Genie 2 help file.

RemoteCare is supported only for follow-up fittings. Do not use RemoteCare for the first or initial fitting, as this is not supported.

Additional system requirements

- PC camera OR external camera.
- Microphone and speakers or headset.
- A RemoteCare account. To sign up for an account, contact your local Oticon representative.
- A stable internet connection with a recommended minimum speed of 1/1 Mbit/s (check with your internet provider).

User system requirements

Oticon Opn S™, Oticon Opn, Oticon Opn Play™, Oticon Xceed, Oticon Xceed Play, Oticon Ruby or Oticon Siya hearing instruments – paired with a user's phone.

- An iPhone, iPad or Android phone. See compatible models and software versions in the following link: www.oticon.global/hearing-aid-users/support/faq/ compatibility.
- A stable internet connection: The recommended minimum speed is 1/1 Mbit/s (check with your internet provider).
- An email account.

Enable Oticon RemoteCare

There are two steps that you must follow before you run RemoteCare. The first one is to create an account and then to enable RemoteCare.

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

Create account

To create an account, open the Oticon RemoteCare invitation email sent by your local representative and follow the instructions.

To enable and run RemoteCare

To start RemoteCare, you must first enable it within Genie 2 and then sign-in. To do so:

- In NOAH, select the relevant user/patient you have the RemoteCare appointment with, and open Genie 2 from NOAH.
 - If you are running Genie 2 in stand-alone mode, in your computer, run Genie 2.
- 2. In Genie 2, in the **Selection** step, in the Task Pane, in the lower left-hand side, click the **RemoteCare** button.
 - If you are running Genie 2 in stand-alone mode, in the Client step, double-click the user to select it, and then from the Fitting step, in the Task pane, in the lower left-hand side, click the RemoteCare button.

To sign in and start an appointment

Note

It is only possible to start an appointment when the user is already present and has already started an appointment and is waiting for the hearing care professional to join the session.

 In the RemoteCare dialog box, in the username or email address field, enter your username or email address and in the password field, enter your password.

- 2. Select the checkbox stating that Tinnitus SoundSupport is not intended for fitting during RemoteCare.
- 3. Click **Sign in**.
 At this point, the user you are connecting to, must have already started the appointment within the app on his phone or device.
- 4. In the **Connect to your client** dialog box that appears, in the field provided, enter the email address of the user you want to connect to, and click **Continue**.
- 5. To establish communication with the user, in the **Waiting room** dialog box, click the **Start an appointment** button.
- 6. To connect to the hearing instrument remotely, in the Genie 2 toolbar, on the upper left-hand side of the screen, click the **CONNECT** button.
- 7. If the computer recognised the instrument, in the **Connect Wireless** dialog box, you should see it under Detected Instruments. Alternatively if the instrument was not recognised, click **Detect**.
- 8. Click Continue.

At this point, if the settings in Genie 2 differ from those saved in the instrument, a **Select Settings** dialog box appears, where you can choose to use instrument data, use session data or start a new fitting.

If instead you see a **Wireless Connection Status** dialog box, ensure Genie 2 has selected the correct instrument and click **OK**.

RemoteCare communicator

The RemoteCare communicator is the interface used to communicate with the user. It allows for text messaging and communication via audio and video between you and the user. The following icons describe the communicator window.

- The • icon enables or disables your camera.
- The icon mutes or unmutes your microphone.
- The Ficon enables or disables text messaging.
- The ood icon refreshes the video stream.

To perform a fitting, upload settings and save

- 1. In the **Fitting** step, if needed, fit the hearing instrument(s) as you normally would, or make the necessary changes to the settings of the instrument.
 - You can also click any of the other organiser steps in the fitting flow to change other settings.
- 2. When you are finished changing the settings of the instrument(s) you must upload the new settings to your instrument. To do this, in any of the organiser steps, in the Task pane, in the lower left-hand side of the screen, in the RemoteCare section, click the Upload button.

In the RemoteCare communicator window, you can see the status of the settings upload.

- It is recommended to click the **Upload** button after every change made to the hearing instrument, to ensure the user receives the changes in real-time, and to act as a safeguard in the event of a sudden lost connection.
- 3. When the settings upload is finished, in the Genie 2 toolbar, on the upper left-hand side of the screen, click the **Disconnect** button. The hearing instrument now restarts.

Note

You can also disconnect the instrument(s) from the End Fitting step.

- 4. To save and end the session, go to the **End Fitting** step and click the **Save and exit** button.
 - If you are using Genie 2 in stand-alone mode, this button may be called Save and go to Client step.

⚠ 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 ear 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.

Transfer Settings

Ensure that while transferring settings, the user does not wear the hearing instruments.

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 in the Client step in Genie 2.

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

Disclaimer

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

Technical information



Oticon A/S Kongebakken 9 DK-2765 Smørum Denmark www.oticon.global

C€ 0543



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 mark

C € 0543 The device complies with Medical Device Directive 93/42/EEC. The four digit number indicates the identification of the notified body.



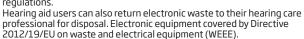
Medical Device

The device is a medical device.



Electronic waste (WEEE)

Recycle hearing aids, accessories or batteries according to local regulations.



Description of additional symbols used on labels



Catalogue number

Indicates the manufacturer's catalogue number so that the medical device can be identified.



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.

