Instructions for use

Genie 2
2023.2

oticon
life-changing **technology**
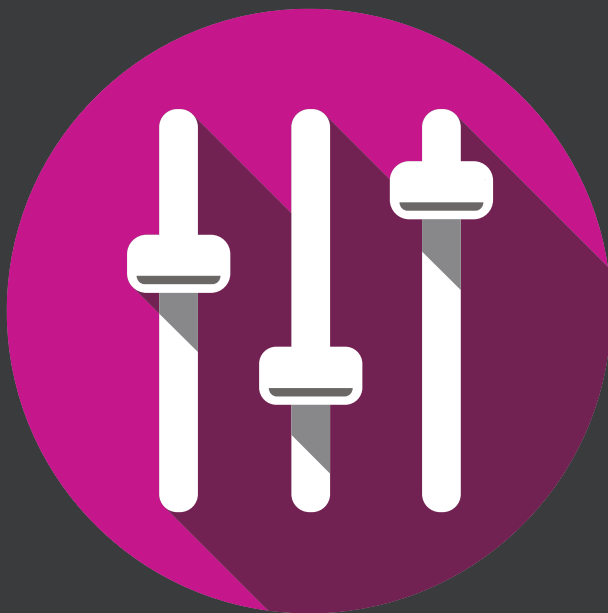
Introduction

The following instructions for use are
valid for Oticon Genie 2 2023.2.

Genie 2 is a fitting software used for Oticon Opn™
and newer hearing aid families.

If you have additional questions about the use
of Genie 2, contact your local distributor.

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

| **About** | Fitting software overview | Warnings | More info |

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 equipment.
Indications for use	There are no indications for use (diagnoses) for the fitting software itself.
Intended user	The fitting software solution is intended to be used by Hearing Care Professionals (HCP) who in this document are referred to as, but are not limited to, Hearing Aid Professionals (HAP), audiologists, ENT (ear, nose and throat) doctors, and Hearing Aid Dispensers (HAD).* The user of the fitting software shall be a hearing care professional who is appropriately trained, has proven competency in professionally assessing hearing, selecting, fitting and delivering hearing instruments, and rehabilitation care to persons with hearing loss. The training of the hearing care professional is in accordance with their specific educational background following national or regional regulations. *The job title may vary from country to country.
User environment	Clinical setting.
Contraindications	No contraindications.
Clinical benefits	See clinical benefits of the hearing aid.

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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First installation

The fitting software installation file is
provided on a USB / DVD drive.

If you are unable to install the fitting software,
contact your local sales representative.

To install the fitting software, open Windows Explorer,
browse to the relevant drive or download location and
double-click the **Setup.exe** file. When starting the installer,
follow the installation instructions on the screen.

The software updater and SoundStudio are
installed together with the fitting software.

Upgrading from older versions of fitting software
If you are unable to upgrade to the current version of the
fitting software, contact your local sales representative.

If you already have a previous version of Genie 2
installed, client sessions will still be visible.

Uninstall the fitting software
Use your operating system software
to uninstall the application.

System requirements
The following are the recommended minimum system requirements to install and use the fitting software:

HARDWARE	CPU	Intel Core i5, 4 cores, 3.2 GHz or faster
	RAM	8 GB
	Free Hard Disk Space	8 GB
	Hard drive	256 GB Solid State Drive (SSD)
	Screen resolution	1920 x 1080
	Ports	USB 2.0 for USB installation and programming devices
	Drive	DVD drive for DVD installation
	Soundcard	Stereo or 5.1 /7.1 surround sound (recommended)
	Accessory	Keyboard and mouse
SOFTWARE	Operating System	Windows 11 or Windows 10 Anniversary update (32/64 bit)

Note
Installation of software on computers that do not meet specific requirements noted above may result in system failures.

Optional tools
• Noah 4 audiology software

> **Note**
> Noah-compatible management systems
> must be HIMSA certified.

• 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

• It is recommended that you protect your data by
  using whole disk encryption (e.g. BitLocker)

Stand-alone fitting software database
When you use the fitting software without Noah software
(in stand-alone mode), you can manually enter or edit
client data. The data is automatically saved in the fitting
software database and used for any subsequent fittings.

> **Note**
> Noahlink Wireless is required when
> connecting Bluetooth-enabled hearing aids
> from Oticon More or newer families.

> **Note**
> HI-PRO 2 is recommended for hearings
> aids that support wired connection.

Fitting software overview

This is an overview of the functionality, features, and tools in the fitting software. 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 in a standard fitting flow.

For further information about any of the features, refer to the built-in help guide. To access the help guide within the software, go to the **Help** menu and then click **Help on Genie 2**.

You can navigate the fitting flow through the horizontal and vertical panes to access different sections and tools.

To display contextual help documentation, press the **F1** key or the "**?**" symbol on the top right hand corner of the screen.

Enter client data

You can select an existing client or manually enter a new client's data such as name and date of birth in the **CLIENT** section. An audiogram can also be added. The use of Noah audiology software automates the data entry process and allows you to bypass it.

Connect hearing instruments

To connect hearing instruments to one of the programming devices, either with cables or wirelessly, you click **CONNECT**.

You can also simulate an instrument by clicking **SIMULATE** and selecting a hearing instrument. This allows you to check possible configurations of a hearing instrument, or to see how tools look and work.

Note
If the connection to one of the hearing aids is lost during the fitting session, the fitting for the missing hearing aid can be continued in simulation mode. Ensure that both hearing aids are connected before saving any updated settings.

Transfer fitting data
You can transfer settings from a fitting session to a new selection of hearing instruments through Transfer Settings tool. The tool starts automatically when new hearing instruments that are different from the current session are connected or selected. You can manually select Transfer Settings via Tools in the menu bar.

Customise individual parameters
You can customise the parameters to meet a client's specific listening needs, and individual acoustic and audiometric parameters in WELCOME, SELECTION and FITTING sections using the available tools.*

For more advanced personalisation, you can select Personalization questionnaire in SELECTION section.

* If the CROS Transmitter is selected for fitting, consider the following important notice.

IMPORTANT NOTICE
Transmitter use in complex listening environments.
The Transmitter is intended for adults and children older than five years. The use of a Transmitter may have an impact on speech discrimination in complex listening situations. Special caution is advised for children from five to eight years of age. Children may be unable to manage interfering, non-speech sound transmitted to their better ear by the device.

Fitting hearing instruments

You can adjust the settings, measure feedback and program hearing instruments in **SELECTION** and **FITTING** sections using the available tools. You can review features and settings with a client and make adjustments using these tools.

End fitting

You can verify and set individual user operational settings for buttons, indicators, and accessories to finalise the fitting session with the client in the **END FITTING** section. You can also see the summary of the hearing aids' features and settings here. You can save settings, session information on the database and hearing aids, generate a report and exit the fitting software.

Additional tools
Real Ear Unaided Gain (REUG)

The REUG tool can be used to take Real Ear Measurement (REM). You can import REUG measurements from Noah, or enter them manually.

Real Ear to Coupler Difference (RECD)

The RECD tool is used to simulate REM by coupler measurement.

REM

The REM tool allows you to set the instruments in measurement mode for use with your REM equipment.

REM AutoFit

With this tool, you can automatically and manually fit hearing instruments to the prescribed target using a compatible REM system.

Feedback Analyser

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

In-situ Audiometry

The In-situ Audiometry tool lets you measure the client's hearing using the hearing aids as transducers. This means the fitting can be fine-tuned to better match the individual ear canal, taking into account the instrument and the acoustic coupling.

Tinnitus SoundSupport

Tinnitus SoundSupport generates sounds for use in a tinnitus management program to help users suffering from tinnitus.

Updater tools

Instrument Updater and Accessories Updater help you update the firmware of hearing instruments and accessories.

Remote fitting

Oticon RemoteCare™ enables you to communicate with a client and make real-time adjustments to a client's hearing instrument(s) remotely.

Be aware that if you cannot upload your changes remotely, a physical visit is necessary. Not all features available in the fitting software are available during remote fitting.

RemoteCare can be used when a valid audiogram is on record and the audiogram has not changed. In extraordinary circumstances you may not be able to perform a hearing evaluation in person. If this occurs, it is recommended that you use an approved remote diagnostic device. For further information, contact your local distributer.

Remote In-situ Audiometry

You can perform remote In-situ Audiometry during the remote fitting session to fine-tune the gain of your client's hearing instruments.

Additional system requirements for the hearing care professional

• Internal webcam or external camera device

• Microphone and speakers or headset

• A RemoteCare account. To sign up for an account, contact your local sales representative.

• Ensure you have a stable internet connection suitable for both sound and video streaming, with a recommended minimum speed of 1 Mbps (upload/download). Check with your internet provider.

• If you are using an operating system older than Windows 11, you may experience problems when logging into RemoteCare. Therefore, it is recommended that you install Microsoft WebView2 Runtime on your computer. Contact your system administrator if you need help with this installation.

System requirements for the client
• Hearing aids paired to the client's phone / tablet

• A compatible Apple or Android phone / tablet. To check for compatibility, visit: www.oticon.global/compatibility

• A stable internet connection suitable for both sound and video streaming with a recommended minimum speed of 1 Mbps (upload/download).

• An email account, or Apple, Google or Facebook credentials.

IMPORTANT NOTICE
The hearing care professional is responsible for obtaining the licence needed to use the remote fitting feature with clients. The manufacturer does not take any responsibility for hearing aid fitting through the app.

IMPORTANT NOTICE
Before performing remote In-situ Audiometry, inform the client that if the internet connection is lost during the procedure, the client must remove and restart the hearing instruments if they are muted or still playing sound.

Data Logging feature

The Data Logging feature is a software supported function of the hearing instrument. With this feature, data generated in the hearing instrument is logged by the software during the fitting sessions (when the hearing instrument is connected to the software). The data may be used to better understand and assess how to optimise the hearing instrument and tailor it to the needs of the client.

IMPORTANT NOTICE
Make sure you are transparent with your client about this feature. The Data Logging feature can be turned off if the client does not want this data logging to happen. You should always respect the client's wishes.

Information about Conversation Activity feature

When the Conversation Activity feature is switched on, it can log the client's cumulative voice activity average over the usage period and in different kinds of sound environments (simple, moderate, or complex). The usage period is defined as time between hearing aid fittings and subsequent follow up appointments.

These log points can be used for targeted fine-tuning and further audiological advice tailored to the client. The log points determine the presence of modulated/speech signals and there is no logging of the actual conversation. The Conversation Activity feature can never log what is being said and it does not provide for voice recognition.

IMPORTANT NOTICE
Before switching on the Conversation Activity feature, make sure it is in line with the wishes of the client and that the client has been clearly informed about how the feature works.

⚠ **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 information
For safety reasons, it is important that you read the Intended Use of the fitting software in the **Introduction** section of this booklet. If you are fitting a hearing aid with Tinnitus SoundSupport, please familiarise yourself with the risks related to the fitting level of the Tinnitus SoundSupport feature, and the recommended wearing times.

The developed SPL in the ears of children can be substantially higher than in average adults. RECD measured to correct target of fitted OSPL90 is recommended.

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 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

The following are definitions that may appear in the Instructions for use for Oticon Genie 2.

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 Regulation 2017/745.
$C \epsilon$ 0123	**CE mark** The device complies with all required EU regulations and directives. The four digit number indicates the identification of the notified body.
MD	**Medical Device** The device is a medical device.
🗑	**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).
GTIN	**Global Trade Item Number** A globally unique 14-digit number used to identify medical device products including medical device software.

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.
UDI	**Unique device identifier** Indicates a carrier that contains unique device identifier information

This medical device complies with
Medical Device Regulation (EU) 2017/745.

Declaration of Conformity is available at the headquarters.

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2023

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

$C\epsilon$ 0123

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