

Starkey **Pro Fit** **User Manual**

Supported products:

Pro Fit fitting software supports
product families introduced in 2023

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Introduction/Intended Use

Introduction

The following guide provides information on Pro Fit fitting software. Pro Fit fitting software supports product families introduced in 2023 and forward. Product visibility in the **Product Simulator** screen varies by market.

Intended Use

Pro Fit is a software medical device intended to allow a hearing care professional to appropriately adjust an air conduction hearing aid’s features and performance to enable the hearing aid to compensate for a patient’s impaired hearing.

Intended User

Hearing care professional

Intended Environment

Clinical setting

Install

Install

Pro Fit fitting software is available in a variety of forms. Installation instructions are provided with each type of installation. We encourage you to work with your sales representative to establish a prosite account with us. This provides you a wide variety of information and gives you access to links for Pro Fit download.

Once Pro Fit is installed, we provide automatic updates when future versions are released. We strongly encourage using that automatic feature to keep the software version up to date.

Additionally, you may contact Customer Support for a USB or DVD copy.

System Requirements

System Requirements

- **Processor Speed:** Intel i7 recommended
- **System RAM:** 8 GB recommended
- **Operating System:** Windows 10, Windows 11
- **Hard Disk:** Hard disk space required to run 4 GB
- **Browsers (for eStore Access, Pro Fit Updater, and TeleHear®):**
 - Chrome™ - latest version
 - Firefox® - latest version
 - Microsoft Edge® - latest version
- **Communications Port for Programmer:**
 - USB port for SpeedPort, SpeedPort 2, NOAHlink, HiPRO USB, and NOAHlink wireless programmers 1 and 2.
- **Audio Hardware:** Sound card and stereo speakers are recommended to take full advantage of media sounds
- **Client Database:** NOAH 4, PatientBase

System Requirements

Optional tools

- NOAH 4 software or PatientBase software
- Internet connection
- Real ear measurement system
- Adobe™ Acrobat Reader™

Database options

Pro Fit fitting software requires a database application. We recommend using NOAH 4 or our proprietary database called PatientBase. For further information on the NOAH application, please contact HIMSA. For additional information on PatientBase, please contact Customer Service.

Pro Fit Overview

Pro Fit Overview

This guide provides an overview of the Pro Fit fitting software. The high-level information in this guide covers general navigation, functionality and tools. For additional information with greater detail, please go to the **Help** menu and click on **Help for Pro Fit**.

The Connect screen is the opening screen and the launch pad for all Pro Fit functions. Features include:

- **Retrieve Session**
 - Open past, saved sessions to view or to push into connected hearing aids.
- **Product Simulator**
 - Review software tools and features without connecting to live devices. Most features are available and show their default settings.
- **Hearing Loss Simulator**
 - The **Hearing Loss Simulator** is a tool to demonstrate the effects of the patient's hearing loss using a variety of sounds. Various display options, visual aids, and drawing tools help facilitate the discussion of the impact of hearing loss.

Pro Fit Overview

Additionally, hyperlinks located at the top right side of the screen:

- **Resources**
- **Ordering**
- **Service**
- **TeleHear**

Select Connect to begin a live session or choose Product Simulator.

Navigation

Once a fitting session has started, either by connecting to hearing aids or by Product Simulator, all fitting screens are available. We recommend using the session type organization for quick access to the most commonly used screens in each session type. Additional fitting screens are ordered by usage and are available by clicking on the three bars (also called a hamburger icon) at the top of the colored bar on the left side of the fitting session.

Pro Fit is organized into three session types: **Preparation**, **Fitting**, and **Follow-Up**.

Pro Fit automatically advances through the session types. You may also change between session types if desired.

Pro Fit Overview

• **Preparation**

- **Preparation** is a session type for preparing hearing aids before the patient arrives. The most common preparation screens, **Experience**, **Programs**, **User Controls**, and **Accessories**, are accessible at the top of the screen. When reading new hearing aids, **Preparation** is the first session type displayed in Pro Fit.

• **Fitting**

- **Fitting** is a session type for the first session with the patient. **Fitting** offers easy access to: **Feedback Cancellor**, **Quick Fit**, **Sound Manager**, **User Controls**, and **Indicators**. Upon reading hearing aids the second time, Pro Fit displays the **Fitting** session type.

• **Follow-up**

- The **Follow-up** session type is the default for all sessions after the initial fitting. The most commonly used adjustments are accessible at the top of the screen: **Data Log**, **Fine Tuning**, **Sound Manager**, **Indicators**, **User Controls**.

Pro Fit Overview

Fitting screen descriptions

- **Quick Fit** – provides convenient accessibility to adjust overall gain, overall output, low frequency gain, high frequency gain, and occlusion.
- **Fine Tuning** makes discreet, frequency-specific adjustments to channel gains and maximum output. Channel adjustments change gain and compression settings and MPO modifies the maximum output. Adjustments can be made to each individual channel, to groups of channels labeled low frequencies, mid frequencies, high frequencies, or ultra frequencies, or to all channels simultaneously. Adjustments vary by product.
- **Feedback Canceller** – adaptive, active feedback cancellation prevents most feedback. For optimal performance, the feedback canceller should be calibrated in the patient's ear. Click on Begin to present the calibration signal in both ears.

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- **User Controls** – tailor the hearing aid controls to the specific needs of each patient. Click on a type of control (i.e., volume) and drag to a gesture and side (i.e., short press - right). Additional user control adjustments include volume and tinnitus range and step size.
- **Experience** – transition patients with varying levels of hearing aid experience from initial, spontaneously accepted gain settings to the final, desired, target-gain settings. Available as a manual or automatic feature.
- **Programs** – configure phone and loop options as well as copy and move programs. The programs bar, located in the center of most screens, provides easy access to selecting program environments based on your patient's need. Additionally, selecting a program environment automatically enables the corresponding speech indicator for that memory.

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- **Indicators** – a wide variety of indicator options includes language and gender for speech indicators as well as many frequency-specific tone indicators. Levels may be set globally or individually for speech and/or tone indicators. Indicators may be played through the hearing aid for counseling through desktop speakers.
- **Sound Manager** – comprised of noise management, adaptive algorithms, and directionality adjustments. The default view shows settings across all enabled programs. Adjustments can be made by clicking the up/down arrows on the setting value or by clicking details for more information.
- **Data Log** – collects and summarizes hearing aid data. View global averages or drill into memory-specific data. Data Log is a valuable tool for counseling and targeting specific hearing aid adjustments.

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- **Audio Streaming** - Adjust the frequency response for streamed input. Additionally, Audio Streaming offers the ability to stream from a paired mobile phone or accessory while adjusting the frequency response. Availability of Audio Streaming varies by family.
- **Accessories** – pair hearing aids to accessories (2.4 GHz accessories may be paired outside of Pro Fit as well) and adjust the level of the hearing aid microphone relative to the stream. Also offers additional adjustments based on paired devices.
- **Frequency Lowering** – a proprietary algorithm characterizes the high-frequency spectral shape and dynamically recreates that spectral shape inside a lower frequency target region. Adjustments include the bandwidth and gain.
- **Tinnitus** – access to enable the tinnitus stimulus and set modulation as desired. Stimulus Personalization guides you

Pro Fit Overview

through testing for the minimum detection levels and minimum masking levels to customize the tinnitus stimulus to your patient's specific needs. Availability varies by product.

- **Speech Mapping** – offers the ability to view and capture inputs in real time. This information is often used for counseling or demonstrating the benefits of amplification. Speech Mapping is only available during a live fitting.
- **Self Check** – performs a diagnostic test of the components in your patient's wireless hearing aids. The diagnostic test can be initiated via Pro Fit or the mobile application.
- **Hearing Aid Test** – a tool that measures the hearing aid's performance.
- **Audiometer** – a tool for conducting in-situ threshold testing through the hearing aids. In-situ Audiometry does not replace conventional diagnostic audiometry.

Pro Fit Overview

- **Verify Comfort** – confirms that loud and soft inputs sound satisfactory to the patient by presenting a sequence of tones across the frequency response curve.
- **TeleHear** – A tool that allows you to make remote adjustments to your patient's hearing aid settings. The TeleHear portal tracks your patients' call history, and manages your office and users' details for remote programming.

Additional screens accessible from the left navigation bar are:

- **Troubleshooting** – a tool used to address patient complaints and provide solutions. Issues can be resolved by applying these solutions directly to the hearing aid(s).
- **Audiology On Demand** – a live remote-assistance tool that allows Customer Service representatives to provide assistance by chatting and/or viewing your desktop and sharing control of your mouse and keyboard. This feature is only available if the PC has Internet access.

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- **Fitting Summary** - provides a quick visual overview of the hearing aid's features and setting information including programs, noise control, indicators, status, etc. for a particular live or simulated fitting.
- **Save and End Session** - Click to save then end the session and return to the Connect screen. Alternately, clicking on the black 'X' in the upper right corner prompts a session save dialog then closes Pro Fit.

Top Navigation

The top, horizontal tool bar of Pro Fit includes six menus:

- **File** – offers typical selection menu: open, save, print, and close
- **Edit** – Undo, redo and copy settings
- **Preferences** – a wide variety of customization options for a personalized fitting experience
- **Tools** – various options most often used during fittings. Most are an additional access point
- **Display** – select from various display and input options. Default: Speech input and predicted real ear response

Pro Fit Overview

- **Help** – this menu comprises help files, specific version number, the EULA, and other help-related items

The secondary tool bar offers quick access to many items that are under the upper tool bar menus. The fitting formula dropdown is conveniently located on this tool bar providing a visual indication of the selected fitting formula.

Setup

Setup

1. Install Pro Fit fitting software.
A series of screens assists you in setting up the software for your region.
2. Connect a programmer to your computer. Compatible options are listed in the System Requirements section of this document.
3. Enter the patient-specific information into your database application and open Pro Fit.
4. Connect the hearing aids to the programmer using the appropriate programmer and connection (i.e., wired or wireless) defined in Cables and Connectors under the **Help** menu.
5. Select the hearing aids by clicking on the hearing aid card. A blue bar at the top of the card indicates that the hearing aid is selected. Once the aids are selected, click Connect.


Setup

Fitting Session with Pro Fit

- After completing the setup process and connecting, the new aids are now at the optimal setting with all features at default. Configure user controls and programs as desired. We recommend that you always run the feedback canceller test with the hearing aids in the ears.
- Upon completion of the fitting session, click on the X in the upper right corner to save and exit. Saving the session stores that session in the database for future retrieval if needed.

Safety Information

We are required by regulations to provide the following warnings:

 **WARNING:** For safety and correct usage, we recommend that you familiarize yourself with the fitting software. Additional resources such as detailed fitting guides and online courses are available on the prosite.

Take special care when setting up the tinnitus stimulus, ensuring that the stimulus level does not exceed a comfortable level for the patient.

Use precaution when fitting a power instrument where the maximum sound pressure capability exceeds 132 dB SPL as you may risk causing damage to the hearing of that patient.

Please follow instructions to remove hearing aids from the patient's ear for certain procedures such as updating firmware.

Clinical Benefit

Pro Fit alone does not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the hearing aids to achieve their intended purpose.


Security Notice

Patient data is private and protection of it is important, therefore please refer to the following:

- Compliance with any and all applicable privacy data and security laws.
- Obtain any required patient authorizations or consents, and provide all necessary and applicable privacy notices to patients when using software.
- Take all reasonable precautions from malicious software by securing your computer systems with up to date antivirus software, install Windows security updates, and activate firewalls.
- Maintain administrative, technical, and physical measures required to maintain appropriate information security with respect to protected health information and compliance with HIPAA and any other applicable privacy and data security laws.

Please note that this is not an exhaustive list.

Regulatory information

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Waste from electronic equipment must be handled according to local regulations




















Consult user manual



Medical Device

Regulatory information

Symbol	Symbol Meaning	Applicable Standard	Symbol Number
	Manufacturer	BS EN ISO 15223-1:2021	5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1:2021	5.1.2
	Date of Manufacture	BS EN ISO 15223-1:2021	5.1.3
	Catalogue Number	BS EN ISO 15223-1:2021	5.1.6
	Serial Number	BS EN ISO 15223-1:2021	5.1.7
	Medical Device	BS EN ISO 15223-1:2021	5.7.7
	Keep Dry	BS EN ISO 15223-1:2021	5.3.4
	Temperature Limit	BS EN ISO 15223-1:2021	5.3.7
	Humidity Limitation	BS EN ISO 15223-1:2021	5.3.8
	Caution	BS EN ISO 15223-1:2021	5.4.4
	General warning sign	EC 60601-1, Reference no. Table D.2, Safety sign 2	ISO 7010-W001
	Refer to instruction manual/booklet	EC 60601-1, Reference no. Table D.2, Safety sign 10	ISO 7010-M002
	Collect Separately	DIRECTIVE 2012/19/EU (WEEE)	Annex IX
	Class II equipment	IEC 60417 Reference no. Table D.1	Symbol 9 (IEC 60417-5172)
	Regulatory Compliance Mark (RCM)	AS/NZS 4417.1:2012	N/A
	Giteki Mark	Japanese Radio Law	N/A
	Direct current	IEC 60601-1 Reference no. Table D.1	IEC 60417-5031
	Recycling Symbol	European Parliament and Council Directive 94/62/EC	Annex I-VII

Notes

[illegible]

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Patent: www.starkey.com/patents