

Inspire^X

USER MANUAL

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Introduction

The following guide provides information on Inspire X fitting software.

Inspire X fitting software supports product families introduced in 2006 and forward. Some of these products are no longer available for new sales, but programming capability continues. Product visibility in the **Simulate Products** screen varies by market.

Intended Use

Inspire X 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.

Clinical Benefit

Inspire X itself does not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the hearing aids to achieve their intended purpose.

Intended Patient Population

Inspire X enables the hearing aid performance and has the same Intended Patient Population as Hearing Aids.

Air conduction hearing aids are intended for people (18 years of age or older) who have been diagnosed by a licensed clinician or audiologist to have hearing loss. The Multiflex Tinnitus Technology is targeted for patients suffering from tinnitus being treated by healthcare professionals. The fitting of the Multiflex Tinnitus Technology should be done by a hearing professional while participating in a Tinnitus Management Program.

Adverse Event Reporting

Any serious incident that has occurred in relation to your Starkey device should be reported to your local Starkey representative and the Competent Authority of the Member State in which you are established. A serious incident is defined as any malfunction, deterioration in the characteristics and/or performance of the device, or inadequacy in the device user manual/labeling which could lead to the death or serious deterioration in the state of health of the user, OR could do so upon recurrence.

Intended User: Hearing Care Professional

User Environment: Clinical Setting

Contraindications

There are no contraindications associated with the Inspire X Hearing Aid Fitting Software.

Install

Inspire X 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 Inspire X download.

Once Inspire X 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

- **Processor Speed:** Pentium® 4 or higher recommended
- **System RAM:** 2 GB minimum, 3 GB recommended
- **Operating System:** Windows® 7, Windows 8 or 8.1, Windows 10, Windows 11
- **Hard Disk:** Hard disk space required to run 1.5 GB
- **Browsers (for eStore Access, Inspire Updater, and remote programming):**
 - Internet Explorer® - latest version
 - Chrome™ - latest version
 - Firefox® - latest version
 - Microsoft Edge® - latest version
- **Communications Port for Programmer:**
 - Serial COM port (or an approved USB to Serial converter) is required for HiPro and HiPro 2
 - USB port for SpeedPort, SpeedPort 2, NOAHlink, HiPRO USB, SurfLink wireless programmer, 2.4 GHz Wireless Programmer and NOAHlink wireless programmer
- **Audio Hardware:** Sound card and stereo speakers are recommended to take full advantage of media sounds
- **Client Database:** NOAH System 3.x or 4, ProHear Deluxe or Standard, ProHear.NET, PatientBase

Optional tools

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

Database options

Inspire X fitting software offers the best user experience when combined with 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.

Inspire X Overview

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

Left Navigation

Inspire X is organized into sections in the vertical, left navigation panel. The Pre-Fitting section is designed to support your needs outside of hearing aid adjustment. This section is composed of:

- **Rationale**
 - **Inspire Online** is for US Only. We do not want to imply EU regulations go down this route.
- **Simulate Products**
 - Select **Simulate Products** to view product families and styles as well as matrices and fitting ranges. After selecting a specific device, click on the Simulate button in the lower right corner to view a simulated fitting. Most fitting screens are available in the simulate mode.
- **Order and Service**
 - **Order and Service** launches eStore to order hearing aids, earmolds and accessories or launches the Service Request Form to process

repairs and returns. **Order and Service** is only available if the PC has Internet access. Additionally, you must have prosite account. A browser such as Internet Explorer 8 or greater, Google Chrome™, etc. and Adobe Reader are required. This is a secure connection to transmit data, therefore, all health information is protected.

- **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. The **Hearing Loss Simulator** is available if it was installed.

The **Get Started** section is designed for connecting to hearing aids either live or in a remote fitting. This section is composed of:

- **Connect Devices**

- **Connect Devices** is the default screen for this section and displays information about detected hearing aids. This screen is where you select your programmer and read the hearing aid. You may also retrieve sessions, from this screen, and load them into the hearing aid.

- **Remote Programming**

- In order to use our remote programming feature, you must first create an account. Click the link for instructions or go to the **Pre-Fitting** section in the left navigation panel and click on Inspire Online. Scroll to the bottom of the page to find information on setting up an account and conducting remote programming sessions in the **Latest QuickTIPS** section.

Fitting is the most often used section of Inspire X and is specifically for fitting hearing aids. This section is accessible after reading a hearing aid or after simulating a fitting from the **Simulate** screen. Adjustments for most screens may be binaural or monaural depending on the side selection buttons located in the center, top portion of the screen. The fitting section is composed of:

- **QuickFit** – 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.

- **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.
- **Manager** - 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.
- **Feedback Cancellor** – 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.
- **Patient Tools** – a trio of features include the hearing aid diagnostic tool called Self Check, the checkboxes to enable viewing custom memories during remote programming, and the settings for Auto Fall Alert. These tools are not available on all products.
- **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.

- **Sound Manager** – comprised of noise management, adaptive algorithms and directionality adjustments. The default view shows setting across all enabled memories. Adjustments can be made by clicking the up/down arrows on the setting value or by clicking details for more information.
- **Tinnitus** – access to enable the tinnitus stimulus and set modulation as desired. Stimulus Personalization guides you 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.
- **Memories** – configure phone and loop options as well as copy and move memories. The memories bar, located in the center of most screens, provides easy access to selecting memory environments based on your patient's need. Additionally, selecting a memory environment automatically enables the corresponding speech indicator for that memory.
- **Accessories** – pair hearing aids to accessories (2.4 GHz accessories may be paired outside of Inspire X as well) and adjust the level of the hearing aid microphone while streaming.

- **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.
- **Fitting Summary** – one stop to view all settings across all enabled memories. Convenient links make it easy to jump to specific areas to make changes as needed.
- **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.
- **Advanced Tools** – this section offers additional tools for hearing care professionals to use, as needed, during hearing aid fittings. Choose from: Audiometer, Expert Assistant, Hearing Aid Test, Speech Mapping and Verify Comfort.

Top Navigation

The top, horizontal tool bar of Inspire X 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
- **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. Simply hover over an icon to view a tool tip descriptor. The fitting formula dropdown is conveniently located on this tool bar providing a visual indication of the selected fitting formula.

Setup

1. Install Inspire X 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: NOAHlink, NOAHlink wireless, and our proprietary programmers.
3. Enter the patient-specific information into your database application and open Inspire X.
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, read device settings, and click Start.

Fitting Session with Inspire X

- After completing the setup process and reading a new hearing aid, a series of screens will prompt you through the initial setup process. These screens may be completed with or without the patient present. If the patient is not present, Inspire X allows you to skip initializing the feedback canceller until a later time.

- After exiting the initial fitting screens, the default screen is QuickFit. Each subsequent hearing aid read after the initial fitting will also begin on QuickFit. Additional frequency response and feature adjustments are accessible through the vertical left navigation. Inspire X adjustments are immediately passed to the hearing aid so that your patient can experience each change. There is no extra step required to 'apply' or 'program' changes to the hearing aid.
- Upon completion of the fitting session, click on the floppy disk icon on the upper tool bar to prompt the save session dialog and exit to the Get Started screen or click the x in the upper right-hand corner to save and then close Inspire X. Saving the session stores that session in the database for future retrieval if needed.

Safety Information

⚠ 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.

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.

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



Consult Operations Manual



Medical Device

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
	UKCA Mark	SI 2002 No 618, as amended (UK MDR 2002)	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



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