

# Fitting System Instructions for Use





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# 1. Introduction

These instructions for use are valid for EXPRESS fit Pro 2020.1.

EXPRESS fit Pro is a fitting software used for Sonic Enchant and newer hearing aid families and models.

A copy of this document is available on https://www.sonici.com/professional-center/professional-support/software-download A printed version can be obtained from your local distributor.

If you have additional questions about the use of the fitting software, please contact your local distributor.

#### Note

For better readability, EXPRESS fit Pro is written in the manual instead of EXPRESS fit Pro 2020.1.

#### Intended use

The fitting software is intended for the fitting and updating of hearing solutions.

The fitting software can facilitate access to real-ear measurement.

## Indications for use

No indication for use.

#### Intended user

Hearing care professional.

#### Use 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.

The target population is the adult population (>18 yrs).

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

# 2. Installation

This USB flash media contains several different software modules:

- FXPRESSfit Pro
- Sonic Firmware Updater
- · EXPRESSfit Pro Updater
- SoundStudio

Installation of the software will install EXPRESS fit Pro. If you already have EXPRESS fit Pro installed, it will automatically be updated.

# Preparing your PC

Before starting the installation, please make sure that your PC hardware and software meet the minimum specified system requirements and that your Windows system is updated to the latest published service pack. Please also make sure that you have administrator rights on the PC.

Some virus software may compromise the installation process and you might have to deactivate your virus scanner to be able to run the installation.

#### Installation

Insert the USB flash media into a USB port. Please start your file explorer, click on the USB flash media and start **setup.exe**. After starting the installer, please follow the instructions on the screen.

# 3. System requirements

Please make sure your PC complies with the following minimum system requirements.

	Processor	2 GHz or faster
HARDWARE	RAM	4 GB or more
	Free Hard Disk Space	8 GB minimum
	Graphics	1280 x 1024 pixels
	Ports	USB 2.0 for USB installation and programming devices
	Sound	(for SoundStudio) 5.1 surround sound card
WARE	Operating System	Windows® 10 (32/64 bit), all editions except ARM platform and Windows® 10 S Windows® 8 (32/64 bit), all editions except RT Windows® 7 SP1 (32/64 bit), all editions
SOFI	Noah	Noah 4 (minimum)
		<b>Note:</b> Noah based Office systems must be HIMSA certified

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

# 4. Getting started with EXPRESSfit Pro

To start a fitting session, enter or open an existing client in your office system and start EXPRESS fit Pro.

In the following chapter, the most important steps of fitting hearing instruments are explained. Please refer to our training material to get more insight into EXPRESSfit Pro fitting software.

#### **Client Data**

Client data, preferred language, fitting rationale, audiogram and REM data can be entered here. Verify and update audiometric parameters to ensure correct gain prescription. This is especially relevant for the fitting of hearing aids for infants and young children.

To detect and connect to the hearing instruments, click **Detect>**.

#### In-situ Audiometry

The In-situ Audiometry tool lets you measure the client's hearing using the hearing aids as transducers. This means that the results will be specific for the instrument and acoustic coupling.

#### Instrument Acoustics

Here you can select hearing instruments for simulation or detect hearing instruments. You can also detect hearing instruments in all screens via the detect button in the menu bar.

#### Acoustic dashboard

After the hearing instrument is selected or connected, the "acoustic dashboard" is shown. There you can enter the acoustic options.

The acoustic dashboard also shows updated information about the hearing aid performance with the selected acoustic options. It can be opened from any screen during the session to view or change the acoustic options. The graph view in the dashboard can be configured in the preference menu.

#### Fit Instrument

This menu contains all the steps necessary for fitting the hearing instruments to the client's hearing loss. You can adjust the gain, assign programs, and measure feedback.

**Adaptation** allows you to manually or automatically over a period of time increase the gain in the hearing instruments from 80% to 100% of the prescribed gain.

**Tinnitus SoundSupport** screen is available to set the Tinnitus SoundSupport function for hearing instruments which include this feature.

## Transfer Fitting

This tool lets you transfer gain, MPO and Adaptation to a new selected hearing aid in a fitting session. These settings are copied – as closely as possible, given the limitations of the target hearing aid – and adjusted to the new acoustic set-up. All other settings remain as prescribed for the target hearing aid. Transfer Fitting is not intended to replace a standard fitting.

#### Feature Selection

This menu offers screens to adjust the hearing instruments' general features and program specific features. For details about the audiological features of our products, please refer to the product information or our training material.

#### Finish session

This menu is used to configure local controls and indicators (beeps), to save and quit your fitting session in the office system database and it allows you to save the data in the hearing instrument.

A copy of the hearing instrument settings is preserved at the beginning of the fitting session and will be saved back to the hearing instruments if you decide to end your fitting session without saving changes.

#### Connection status indicator

It informs you about the connection status of the hearing instruments to the programming device at any time during the fitting session.

The indicator can show the following connection states:

- moving dashed lines indicate connection and pairing in progress;
- a solid green line indicates hearing instruments are connected;
- moving dashes in blue and red indicate data transfer in progress.

If the connection to the hearing instruments is interrupted, a conflict dialog box will inform you. In this case, you can continue in simulation mode and connect the hearing instruments later or try to re-connect to the hearing instruments.

For further guidance regarding EXPRESS fit Pro, please refer to our training material and the help file.

# 5. Sonic Firmware Updater

You can start this updater from the Windows start menu or from EXPRESS fit Pro. Make sure that your computer is online. When you update hearing instruments, make sure that your patient is not wearing the hearing instruments while updating. Connect the instruments with a cable connection. Do not disconnect the instruments while updating.

After the update, the instruments will be set back to factory settings. Restore the client's specific settings before giving the hearing instruments back to the client and pair them with your client's remote control. Provide your client with the latest version of the "Instructions for Use" booklet.

For a detailed guide about the updater, please refer to our training material and the EXPRESS fit Pro help file.

# 6. EXPRESSfit Pro Updater

With the updater you can download updates and new releases when they are available. It opens when you start Windows and checks for new updates. Make sure you set the preferences correctly so that the software is not unintentionally downloaded and installed at an inconvenient time.

For a detailed guide about the updater, please refer to our training material and the EXPRESS fit Pro help file.

# 7. Warnings 🛆

To avoid possible client injury or hearing aid failure, for your personal safety and to ensure correct usage, you should familiarize yourself fully with the following general warnings before using the 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

For safety reasons, always read the Intended Use of the fitting software, the risks related to the fitting level of the Tinnitus SoundSupport feature, and the recommended wearing times.

#### Connection

Take care not to lose the wired or wireless connection to the hearing aid 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 molds when fitting children

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#### **Firmware**

For safety reasons, always ensure that the client is not wearing the hearing aid during a firmware update, as the updated hearing aid will be reset to factory settings after the update. Moreover, do not give the hearing aid to the client before restoring user settings.

Ensure that the serial number of the connected hearing aid corresponds to the serial number registered in the office automation system for the relevant client. Always note the firmware version of the hearing aid before and after a firmware update.

Ensure 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 client about limiting the use of the 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 Instructions for Use for the hearing aid, always enter the maximum wearing time per day. Tinnitus SoundSupport is not intended for clients below 18 years of age.

#### Power instruments

For safety reasons, caution should be taken when selecting, fitting and using a hearing aid where the maximum sound pressure capability exceeds 132 dB SPL (IEC 711) as there may be a risk of damaging residual hearing of the hearing aid user.

#### Transfer Fitting

Your client must not wear the instruments while transferring a fitting.

# In-situ Audiometry

In-situ Audiometry should not be used for diagnostic purposes. Make sure that you add an audiogram in NOAH or the Client step in EXPRESSfit Pro before you conduct In-situ Audiometry. Remove any Real Ear Fit results before you conduct In-situ Audiometry.

Make sure you carry out In-situ Audiometry in a quiet area.

Symbol	Description
M	Manufacturer The product 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.
C€xxxx	CE mark The product complies with Medical Device Directive 93/42/EEC. The four-digit number indicates the identification of the notified body.
<u>^</u>	Warnings Text marked with a marking symbol must be read before using the product.
X	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).
USB 1	Consult the Instructions for Use
ECREP	Authorized representative in the European Community Indicates the authorized representative in the European Community.
MD	Medical Device Symbol

# 8. Disclaimer

The manufacturer does not assume any liability for compliance with local requirements regarding fitting of hearing aids. It is entirely your responsibility as the user of EXPRESSfit Pro to ensure that you have the required training and/or authorization for fitting hearing aids. The manufacturer does not take responsibility for the consequences of using the fitting software outside intended use or warnings.

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