Cochlear®

Cochlear™ Osia® Fitting Software 2

User Guide

Version 2.1

.msi version

FOR PROFESSIONALS

For a printed version of the Osia Fitting Software 2 User Guide, please contact your local Cochlear representative

Introduction

Cochlear™ Osia® Fitting Software 2 is used to program the Cochlear Osia 2 Sound Processor and the Cochlear Osia 2(I) Sound Processor. Osia Fitting Software is to be used by hearing care professionals only. Product availability is subject to regulatory approval in the respective markets.

The Osia Fitting Software 2 is delivered in a zip package. Each delivery of Cochlear Osia Fitting Software 2 includes two software applications (MSI file):

- the fitting software (e.g., OFS 2.1)
- Cochlear Fitting Suite (e.g., CFS 1.7)

The Osia® Fitting Software 2 can be used as a module in office file systems (such as Noah™), or in standalone mode. The Cochlear Fitting Suite is a standalone application which guides the user to a fitting software to use for a specific sound processor model. This is also the application you open through Noah. The Cochlear Fitting Suite icon is indicated at left.
Each Cochlear fitting software delivery may have an updated version of the CFS included due to bug fixes or improvements. It may not be possible to open the installed Cochlear fitting software from the CFS if the installed version is too old. The latest version on the CFS will support all older versions of the fitting software. It is therefore important that the latest version of the CFS is always installed on the

computer. This is also the reason why there needs to be separate MSI installation files for the CFS, BFS 5, BFS 6 and OFS as they need to be possible to install/uninstall separately

The clinic is responsible for maintaining a secure IT environment.

Installation instructions

The following requirements need to be met to run Osia Fitting Software 2, version 2.1:

Hardware requirements (minimum)

- Processor and memory according to requirements of operating system
- Free hard drive space: 1GB
- System RAM: 2GB (4GB recommended)
- USB for Hi-Pro 2 or Noahlink Wireless
- Keyboard and mouse
- Screen

** If lower .NET version is installed, .NET version will be upgraded during installation.*

Software requirements (minimum)

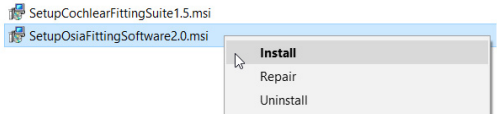
- Windows 11 21H2 or later recommended, Windows 10 Anniversary Update (Version 1803) or later (64 bit), Windows 8.1 (64 bit).
- Compatible with Noah 4.9 or later (Noah 4.10 or later recommended). Configuration of the Noah server and client PCs to use TLS 1.2 is rcommended.
- Adobe Acrobat Reader 9 or equivalent.
- The windows feature NTVDM may need to be installed on Windows 8.1 or later. You will be prompted by Windows to install NTVDM if it is required.
- .NET framework 4.6.1 or later (.NET framework 4.7.2 recommended)

If running in a Noah 4 environment, you are required to install the following component prior to installing OFS 2:

- Visual C++ 2017 runtime files (vcredist x86 version 14.13.26020.0 or higher)

Basic MSI-instructions

The MSI-format (Microsoft Installer) has built-in features for handling the installation.
There is support for Install, Repair and Uninstall via a right-click.



If a command prompt solution is preferred there are many more options.
Here is a short list of the most commonly used:

Switch	Feature	Feature
none	Installs package	msiexec /i SetupOsiaFittingSoftware2.x.msi
/x	Uninstalls package	msiexec /x SetupOsiaFittingSoftware2.x.msi
/qn	Quiet mode without UI. Installation will run without GUI behind the scenes and will not show any dialogs.	msiexec /i SetupOsiaFittingSoftware2.x.msi /qn or msiexec /x SetupOsiaFittingSoftware2.x.msi /qn

Please read Microsoft MSI documentation for all built-in features.

Upgrade

If other versions of Osia Fitting Software 2 and the Cochlear Fitting Suite are already installed on the computer, these need to be uninstalled before proceeding with an upgrade. Please check “Add and remove programs” to be sure.

Installation of Osia Fitting Software 2

To install Osia Fitting Software 2 please run both setup files SetupOsiaFittingSoftware2.x.msi and SetupCochlearFittingSuiteX.x.msi. Noah registration will be performed as part of the setup (custom action). No other actions are needed to install the software. The setup will install two packages on the computer, as described in the tables below.

Package name	Cochlear Osia Fitting Software 2.x
Setup file name	SetupOsiaFittingSoftware2.x.msi
Installation drop location	C:\Program Files (x86)\Cochlear\Cochlear OsiaFittingSoftware2.x
Short description	Contains OFS executables, library files and mandatory material.
Mandatory package	Yes

Package name	Cochlear Fitting Suite
Setup file name	SetupCochlearFittingSuite X.x.msi
Installation drop location	C:\Program Files (x86)\Cochlear\Cochlear Fitting Suite
Short description	Contains Cochlear Fitting Suite executables and library files.
Mandatory package	Yes

When using Osia Fitting Software the clinic is responsible for storing patient information securely as required by local regulations.

Audit trail

As an audit trail is mandatory for Osia Fitting Software 2.1, it is required to run the following command after installation: **{Software executable filename} Createdatabase**

To activate login through Active Directory:

- Create a new or use an existing Active Directory security group
- Add all users who should have access to Osia Fitting Software 2 to this group
- Start the installation of Osia Fitting Software 2 (version 2.1 or later)
- In the installation pop-up tick the box “Change to Active Directory security group”
- Add the name of the Active Directory group where your Osia Fitting Software 2 users are added (only group name, leaving out the directory name)
- Click Validate to allow the installation to check that the Active Directory you entered is available
- Click Install to continue the installation

Intended use

The Cochlear™ Osia® System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Osia Fitting Software 2 is intended to be used by trained hearing care professionals to individually program an Osia 2 Sound Processor and modify hearing profiles in order to provide comfortable and usable gain for Osia 2 System recipients.

Getting started

There are two ways to start fitting software; in standalone mode or from a patient management system, e.g. Noah.

Using standalone mode

Start the program by clicking on the Cochlear Fitting Suite icon. In the Fitting Suite, choose the sound processor family that you would like to program and click the start button to open the fitting software.

Using Noah

Select your patient in Noah. For more information on this step, please refer to the appropriate Noah user guide. Select the most recent audiogram that includes unmasked bone conduction thresholds prior to fitting to provide the most accurate prescription. Start the Osia Fitting Software by clicking on the Cochlear Fitting Suite icon within Noah. In the Fitting Suite, choose the sound processor family that you would like to program and click the start button to enter the fitting software.

Login and audit trail

To prevent unauthorized persons to access any data in Osia Fitting Software, the user needs to log in to the system. The login will also enable an audit trail within the software, which logs and saves activities to be accessed by a user at a later stage. The login and audit trail is required in order to adhere to cyber security standards.

How to log in to Osia Fitting Software

- If Osia Fitting Software 2 is started in Noah 4.9 or later, the Noah login will be sufficient. No additional login is needed. When using Noah 4.9, encryption of patient database needs to be activated.
- If Osia Fitting Software 2 is started in standalone, in an older version of Noah, or any other office system, there will be a need to log in to the Osia Fitting Software using your Windows username and password.
- If Osia Fitting Software 2 is left open and not used for some time, the user will be prompted to log in before accessing the software.
- For each user account used to access Osia Fitting Software, it is important:
  - that the user has a unique username and password;
  - that the password is not left empty;
  - that the user must select a strong password.

Backup and restore audit trail

Audit trail data is saved locally, and it is the responsibility of the clinic to continually perform a backup of the audit trail. In the unlikely event that the audit trail data file has been removed, it will not be possible to start the software until it has been restored. To restore the audit trail, the backup needs to be used.

To perform a backup of the audit trail, visit folder: **C:\ProgramData\Cochlear\Cochlear Osia Fitting Software 2 Common\AuditTrail\2.1.2** and copy following files: **1.dat** and **AuditTrailLog.db**

To restore from a backup file, copy these backup files into to the same folder listed above. If the audit trail cannot be restored, it is possible to replace it by re-installing the fitting software. Previous entries in the audit trail are then lost.

Connecting

The Cochlear Osia 2 Sound Processor can only be programmed using compatible programming interfaces. When programming an Osia 2 Sound Processor for the first time, a wired interface is needed together with the Cochlear provided CS45 cables.
Compatible programming interfaces are:
For first fittings: Hi-Pro 2.
For follow-up fittings: Hi-Pro 2 or Noahlink Wireless.

Using a Hi-Pro2 interface

When using a Hi-Pro 2 interface you must connect in the following order:

1. Connect the Hi-Pro 2 to the computers USB port
2. Open the Osia Fitting Software 2, version 2.1
3. Turn the sound processor ON and make sure the LED is blinking
4. Connect the programming cables to the sound processor

⚠ **CAUTION:**
Programming interfaces for cochlear implants should never be used to program any Osia 2 Sound Processors, unless otherwise specified by Cochlear.

NOTE:
In a bilateral refit session please be sure to connect the right and left sound processor on the correct sides when using the Hi-Pro2.

NOTE:
The sound processor must be programmed with a fresh high power or implant battery.

The icons at the bottom of the screen indicate the connection status throughout the fitting.

Selecting workflows

Several workflows have been provided to guide you through different fitting scenarios. You will be able to proceed to the next recommended screen by clicking Next in the footer. Information on the different workflows is available in the selection screen.

NOTE:
You can use the top menu throughout the fitting to access all screens available.

NOTE:
If you need to change to a different workflow during a fitting, this can be done by opening the Connect dialog. If you choose to change workflow, data in the current session may be lost.

The options available in the top menu are shown in the table below:

Patient	Prescribe	Fitting	Save
• Patient Information	• Audiogram • BC Select • BC Direct	• Adjustments - *Hearing Mentor* - *Fine Tuning* - *Program Settings* • Active Gain • General Settings • Wireless Setup	• Save

Digital Link

The Digital Link Calibration (DLC) calibrates the individual gain baseline and measures the coil to coil distance. Run the DLC by clicking start. It is strongly recommenced to run the DLC on the first fitting. If the calibration is skipped, the OFS will set a default value. To perform the DLC you need a wired interface.

⚠ **WARNING:**
Instruct your patient that they might hear loud tones during the Digital Link Calibration.

Test	To start the calibration press **Test**
Cancel	To cancel the calibration press **Cancel**
Retest	To run the calibration again press **Retest**

Feedback Analyzer

Measures the patient's individual feedback path to reduce the risk for feedback. This test will last 10 seconds and the level will never exceed 73 dB HL. The test will provide a personalized feedback curve based on the user's anatomy (individualised stable gain curve). Make sure that the patient remains still and quiet during the test, and that the sound processor is in place on the patient's head.

NOTE:

If the outcome of the feedback test is not as expected, you can redo the measurement by clicking **Retest**.

WARNING:

Inform the patient that they may experience a high level of noise during the Feedback Analyzer test.

If needed, the feedback measurement can be stopped by clicking **Cancel** at any time during the test.

Datalogging

Enables you to track how the patient has used the sound processor since the last fitting with respect to the different Programs and in different Scenes.
The Scene Classifier will log seven different environments: Quiet, Speech (Soft), Speech (Loud), Speech in Noise (Soft), Speech in Noise (Loud), Noise (Soft) and Noise (Loud). These can be viewed under Scenes. For most fitting flows, the default will be to reset the datalogging upon save. You are, however, able to choose to continue or reset the datalogging in the save screen if that option is available for the chosen workflow.

Patient information

Enter information about the patient and the hearing care professional if running the fitting software in standalone mode. If you have previously saved patient data, click the Import button to import the patient data file from where it is stored. The applicable file format is .nhax or .enhax. Patient files can be both imported and exported from Noah. When using Noah, this section will contain Noah data and will be locked for modification.

Audiogram

When in standalone mode, enter the unmasked bone conduction thresholds in order to provide the most accurate prescription. When using the software as a module in Noah, the latest audiogram will be imported by default. For cases of single-sided deafness, make sure to also include the thresholds of the hearing ear.

When in standalone mode, it is possible to copy audiograms from one side to the other side. Both bone and air conduction thresholds will be copied.

BC Select

To match the patient's individual profile, make sure to select the options that best describe him/her:
Patient: Child or Adult as appropriate
Bilateral/Bimodal: On for a binaural fit; off for monaural fit
Indication: Mixed/Conductive or SSD as appropriate

BC Direct

This measures the patient's bone conduction responses directly through the sound processor. A pure tone test signal will be used by default, however, a warble tone may be selected.

Thresholds can be measured using either a pure tone or a warble tone.

To play a tone, click the Tone button or press the space bar.

In order to provide the most accurate measurement, the sound processor microphones are automatically muted during the test. If you need to communicate with the patient or give instructions, use the Talkback button to switch on the microphones.

To adjust the Talkback volume use the slider.

NOTE:
Perform the BC Direct measurement in a quiet room.

Hearing Mentor

This task lets you quickly and easily make general changes to the sound processor based on typical patient requests. The parameters include adjusting overall loudness, sound quality, the patient's own voice and performance in noise.

Fine tuning

Adjust the gain (soft and loud gain) and output levels per channel (10 available handles, 4 as default) for each program in the sound processor. You can create up to four programs.
Multiple programs can be selected for simultaneous adjustment by selecting the first program and then using Shift + click to select a row of programs, or Ctrl + click to select specific additional programs.
Click the Recalculate button if you need to return to the initial prescription for the patient's sound processor. Click the Feedback Analyzer or connect button to perform a new measurement or remove a previous value.

Program settings

Program settings can be accessed by clicking the program icon in either the Fine tuning, Hearing Mentor or Active gain screen. In program settings you can adjust, on a per-program basis, the settings for Feedback reduction, Directionality or Noise reduction. Directionality and Noise reduction will be directed by SmartSoundIQ. You are also able to represcribe to linear prescription for a specific program.

Active Gain

Active Gain allows for the customisation of gain settings per scene. Select the sound environment you wish to modify and adjust depending on your patient's need.

General settings

Changes in general settings will adjust the settings that affect all programs in the sound processor, such as volume control or visual indicator (if applicable), as well as control the volume and frequency level of beep alerts in the processor.

Wireless setup

Pair wireless devices to the sound processor by:

1. Clicking the icon representing the device that you would like to pair.
2. Pressing the device's pairing button to activate its pairing mode. The device will then be paired automatically, and the icon will change to an active state (yellow).

The serial number of the paired wireless device can be added. This information will be included in the session report for easy access when needed. To change the serial number, click on the existing one to edit. To unpair the wireless device, click on the device icon to change to unpaired state (white).

NOTE:
Pairing a wireless device will increase the battery consumption of the sound processor by 2-4%, make sure that the patient does not have unused devices paired with their sound processor.

Digital Link settings

Digital Link settings are accessible when using the Hi-Pro 2.
The described features are not applicable for the OSI100 implant.

For **OSI200 Version 1.0**: Access to adjust the Audio Signal Offset and the Low-pass Filter. These features are used for fine tuning clarity of sound and low-level noise as needed.

For **OSI200 Version 2.0** and **OSI300**: Access to adjust the Low-pass Filter and turn on System Noise Manager. These features are used for fine tuning low-level noise as needed. When the System Noise Manager is activated it is recommended to redo BC Direct and the Feedback Analyzer measurement.

NOTE:
Adding only the Low-pass Filter will increase battery consumption.

Save

The Save session screen provides an overview of the programs and functions that will be saved on the sound processor. By default, the session will be saved to both the sound processor and to the file system (Noah or Export if using standalone mode).

NOTE:
If you are using standalone mode, you will be able to export patient and audiogram data and save it on your computer/server when clicking Save. The patient files can be selected for export in formats of .nhax or .enhax. Do not disconnect the sound processor until you have received confirmation that saving is complete.

NOTE:
Changes made during the programming session are made directly in the sound processor but must be saved to be made permanent.

Session report

The session report is a printable PDF document that includes useful information for both the patient and the clinician. The session report can be printed from the save screen.

Serious incidents

Serious incidents are rare. Any serious incident in relation to your device should be reported to your Cochlear representative and to the medical device authority in your country, if available.

Support

If further instructions are needed or you need help troubleshooting please contact your local Cochlear representative.

Key to symbols

Please refer to the list below for explanations:

MD	Medical device	Rx Only	By prescription
	Consult instructions for use	UDI	Unique device identifier
REF	Catalogue number		Manufacturer and date of manufacture
	Caution		

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