Cochlear®

# Cochlear™ Baha® Fitting Software 7

## User Guide

Version 7.0

.msi version

EN

FOR PROFESSIONALS

*For a printed version of the Baha Fitting Software 7 User Guide, please contact your local Cochlear representative.*

# Introduction

Cochlear™ Baha® Fitting Software 7 is used to program the Cochlear Baha 7 Sound Processor. Baha fitting software is to be used by hearing care professionals only. Product availability is subject to regulatory approval in the respective markets.

The Baha Fitting Software 7 can be used as a module in office file systems (such as Noah™), or in stand-alone mode. The Cochlear Fitting Suite icon used to access the software is indicated at the left. All installed fitting software is accessible in the Cochlear Fitting Suite.

The clinics using the Baha Fitting Software are responsible for maintaining a secure IT environment.

## Intended use

The Cochlear™ Baha® System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Baha® Fitting Software is used to program a Cochlear™ Baha® Sound Processor and modify hearing profiles in order to provide comfortable and usable gain for Baha® System recipients.

## Intended users

Baha® Fitting Software is intended to be used by trained hearing care professionals, such as audiologists.

## Indications

The Cochlear Baha System is intended for the following patients and indications for use: Patients of any age for use with the Baha Softband, Baha SoundBand™ (or headband) or Baha SoundArc™. Patients aged 5 and older for use with the Baha auditory osseointegrated implant system.
Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL.
Bilateral fitting is intended for patients who meet the criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single-Sided Deafness; SSD). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.
Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

## Intended clinical benefits

The Baha® Fitting Software functions as a part of a Cochlear™ Baha® bone conduction system. Most recipients of a bone conduction hearing solution will experience improved hearing performance and quality of life compared to unaided listening.

## Performance characteristics

The Baha Fitting Software 7 can be used to modify parameters available within the Baha 7 Sound Processor and is limited to the performance characteristics of the Baha 7 Sound Processor.
Within the Baha Fitting Software 7 it is possible to identify the patient's in-situ bone conduction thresholds by using the BC Direct function (test is performed in 5 dB steps in the frequency range of 250 Hz–8000 Hz). It is also possible to identify the individual feedback performance by using the Feedback Analyser (duration 1 to 12 seconds at <73 dB HL) and fine tune the prescribed gain in 1 dB steps at the frequency range of 250 Hz–8000 Hz in 10 available handles.

## Installation of BFS 7

Download the software by clicking the link provided to you by your Cochlear representative which leads to the Cochlear Software Distribution System (CSDS) and follow the on-screen instructions. You are required to install the software from a local hard drive (for example C:) and not a network drive or removable media.

The download contains two different .msi packages; one for the Cochlear Fitting Suite (CFS) and the other for the Baha Fitting Software (BFS). CFS is a stand-alone application which guides the user to select the correct fitting software to use for a specific sound processor model. This is also the application which is launched through Noah. Both applications need to be installed on the computer to perform a fitting. The fitting software and the CFS can be installed in any order.

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 following table.

The installer can also be run interactively (non-silently) by right-clicking the MSI file and choosing the action to take.

| Package name | Cochlear Baha Fitting Software 7 |
|---|---|
| Setup file name | `SetupBahaFittingSoftware7.msi` |
| Installation drop location | `C:\Program Files (x86)\Cochlear\Cochlear Baha Fitting Software 7` |
| Short description | Contains BFS executables, library files and mandatory material. |
| Mandatory package | Yes |

| Package name | Cochlear Fitting Suite |
|---|---|
| Setup file name | `SetupCochlearFittingSuite.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 |

## Uninstall previous version of CFS/BFS

Earlier versions of the CFS/BFS shall always be uninstalled before installing the latest version. See “Step 1 – identify latest CFS version in the installation packages received:” on page 9.

Regarding the fitting software, earlier minor versions and revisions shall be uninstalled before installing a later minor version. However, a new major version does not replace an earlier major version and shall therefore be left on the computer to ensure fittings may continue with the compatible sound processors.

The version of the fitting software is defined as:
<Major>.<Minor>.<Build>.<Revision>

Build is only for internal use and traceability and can be disregarded in this case.
Example: Version 2.0.xxxx.6 is a newer version than 2.0.yyyy.5 and should be updated.

Example: Version 2.1.xxxx.0 is a newer version than 2.0.yyyy.5 and should be updated.

Example: Version 5.4.xxxx.5 should not be replaced by version 6.1.yyyy.62

**Note:**
The naming of the MSI file will include its software version for clarity.

## Verifying that the latest version of CFS is installed

It is essential that the latest CFS version is installed on the computer for all fitting software's installed on the same computer to work. It may not be possible to open a selected fitting software from the CFS if the installed version is too old. But the latest version of the CFS will always support all older versions of the fitting software. Please perform the following steps for CFS identification and installation.

### Step 1 – identify latest CFS version in the installation packages received:

If multiple zip files have been delivered for installation, compare the CFS version in each zip file and identify the latest version CFS MSI file.

Example: The fitting software is to be installed.

- BFS 7.0.X, containing CFS version 1.6.XXXX.0

In this case Cochlear Fitting Suite version 1.12 is the latest version, and version 1.6 shall not be installed.

### Step 2 – compare latest CFS version in the installation packages to version already installed:

If there is already a CFS installed on the computer, compare the latest version of CFS identified in step 1 to the version already installed.

Example: The fitting suite versions are different when comparing what is currently installed to what is provided in the MSI file.

- From Step 1: CFS version 1.12.XXXX.0 identified on MSI file.
- CFS version currently installed on device: CFS version 1.6.XXXX.0

In this case Cochlear Fitting Suite version 1.6 should be uninstalled and version 1.12 should be installed.

## Decision Tree

*"Fig.1: Installing Baha fitting software" on page 10.*
*"Fig.2: Installing Cochlear Fitting Suite" on page 11.*

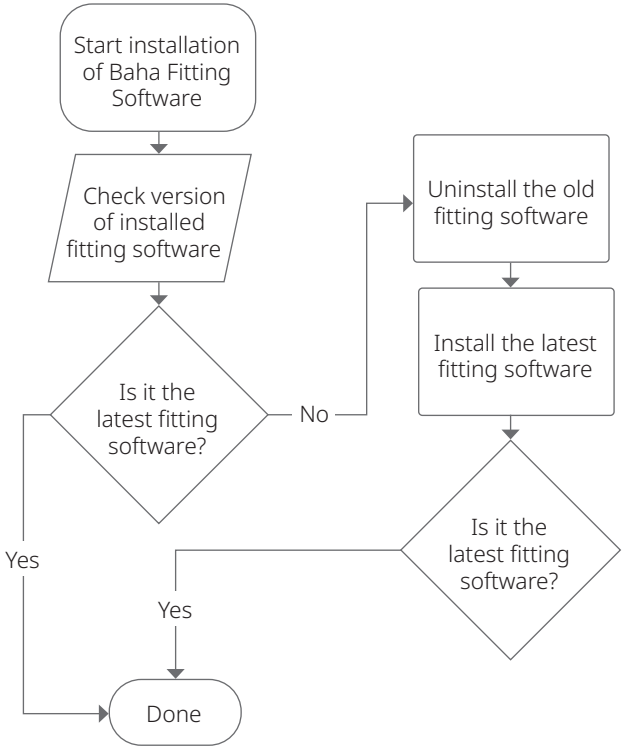



*Fig.1: Installing Baha fitting software*

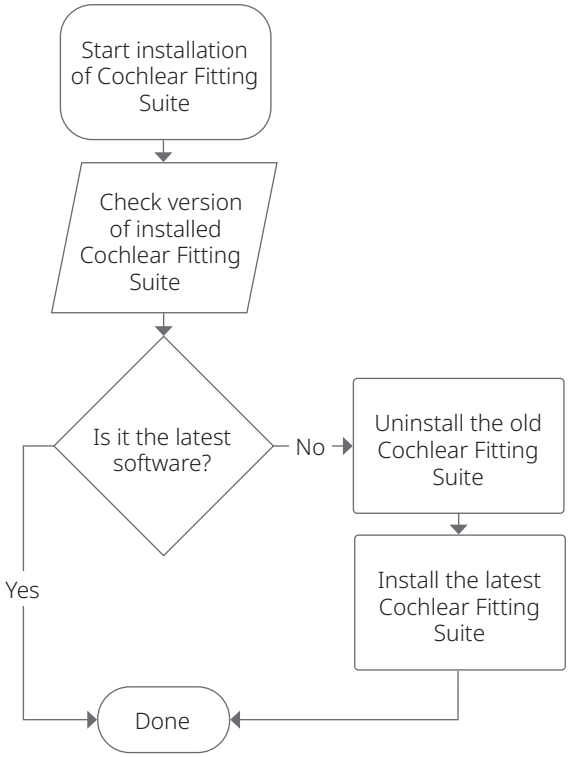
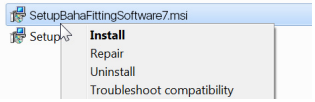



*Fig.2: Installing Cochlear Fitting Suite*

### 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 | Example |
|---|---|---|
| `none` | Installs package | `msiexec /i SetupBahaFittingSoftware7.msi` |
| `/x` | Uninstalls package | `msiexec /x SetupBahaFittingSoftware7.msi` |
| `/qn` | Quiet mode without UI. Installation will run without GUI behind the scenes and will not show any dialogs. | `msiexec /i SetupBahaFittingSoftware7.msi /qn` or `msiexec /x SetupBahaFittingSoftware7.msi /qn` |

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

### Hardware requirements

- Processor according to requirements of operating system.
- Screen resolution – 1920 x 1080 px.
- 2 x USB A ports for Noahlink Wireless.
- 10 GB of free Solid State hard drive space.
- 4 GB of RAM (12 GB recommended).
- Keyboard and mouse.

### Software requirements prior to installation

- Windows 10 (64 bit) version 2004 (Windows 11 21H2 or later recommended).
- Compatible with Noah 4.13 or later. Configuration of the Noah server and client PCs to use TLS 1.2 is recommended.
- You will be prompted by Windows to install NTVDM if it is required.
- .Net 8.0 or later.

## Getting started

### Using stand-alone 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 Baha 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 Baha 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 are required to adhere to cyber security standards.
In BFS 7 the "createdatabase" command that creates an audit trail database is included into the msi-package logic and there is no need to run it separately after installation.

### How to log in to Baha Fitting Software

- If Baha Fitting Software is started from Noah, no additional login is needed. We strongly recommend encryption of the Noah database.
- If BFS is started in stand-alone mode there will be a need to log in to the Baha Fitting Software using your Windows username and password.
- If Baha Fitting Software 7 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 Baha Fitting Software, it is important that:
  - the user has a unique username and password;
  - the password is not left empty;
  - the user selects a strong password.

### Back up 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 Baha Fitting Software 7 Common\ AuditTrail and copy following files: 1.dat and AuditTrailLog.db

To restore from a back-up file, copy these back-up files into to the same folder listed previously. 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

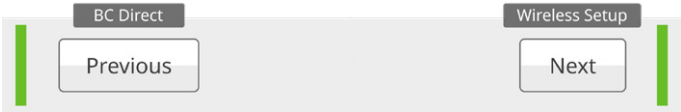
Connect the sound processor to the computer using a Noahlink Wireless programming interface. Please make sure that Noahlink Wireless is plugged in before launching the Baha Fitting Software. To connect to the sound processor, switch the sound processor off and back on to activate Detect mode. Always use a fresh battery during programming.

You will be asked to specify which side each sound processor should be fitted to. Verify which side the sound processors are fitted to by either checking the serial number or clicking the Tone button, and then click Connect.

The black icon at the bottom of the screen handles the disconnection and reconnection of the sound processors 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 step by clicking Next in the footer. Information on the different workflows is available in the activity selection screen.




**Note:**
You can use the top menu throughout the fitting to navigate freely within the software.

**Note:**
If you need to change to a different workflow during a fitting, this can be done by opening the Connect dialog (by clicking the black icon with the arrows pointing towards each other). Unsaved data in the current session will be lost by changing the workflow.

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

| Patient | Prescribe | Fitting | Finalise |
|---|---|---|---|
| • Patient Information | • Audiogram<br>• BC Select<br>• BC Direct | • Adjustments<br>- *Hearing Mentor*<br>- *Fine Tuning*<br>- *Program Settings*<br>• Active Gain<br>• General Settings<br>• Wireless Setup | • Session Report<br>• Save |

## Feedback Analyser

Measures the patient's individual feedback path to reduce the risk for feedback. This test will last from 1 second up to 12 seconds and the level will never exceed 73 dB HL. The test will provide a personalised 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 revert to the default feedback curve by clicking Clear.

Clear

The Feedback test can be accessed at any time via the adjustment screen.

**Caution:**

Inform the patient that they may experience an elevated level of noise during the Feedback Analyser test.

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

Cancel

## Background noise indicator

When starting the Feedback Analyser measurement or the BC Direct screen, the fitting software will run a background noise check. If background noise is detected, there will be a notification to the clinician and suggestion to lower the background noise or to move to a quieter area as background noise might affect the testing.

## Data logging

Enables you to track how the patient has used the sound processor since the last time the data log was reset with respect to the different Programs and in different Environments.
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 Environments. For most fitting flows, the default will be to reset the data logging upon save. You are however able to choose to continue or reset the data logging 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 stand-alone 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 editing.

## Audiogram

When in stand-alone mode, enter the unmasked bone conduction thresholds 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 stand-alone 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 them.
Start by choosing the applicable system:
Baha Connect System, Baha Attract System, Baha Softband, Baha SoundBand™, Baha SoundArc™.

Continue by choosing the following:

- Patient age group: Infant, Child, or Adult as appropriate.
- Bilateral/Bimodal: On for a binaural fit; off for monaural fit.
- Indication: Mixed/Conductive or SSD as appropriate.
- Battery door: Tamper-resistant or standard.

## Verification of fitting

The verification module, using VerifitLINK™ gives the clinician the possibility to verify the sound processor fitting in real time and apply (or discard) suggested changes. The module is accessed via the adjustment screen. To use the module, the clinician must select a verifiable prescription model. To perform the verification, the clinic needs to have access to the Verifit® 2 hardware, sold and distributed by Audioscan. Follow the on-screen instructions for more details on how to use the module.

## 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.

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. When measuring BC Direct for a Baha Attract System patient, allow the Baha SoftWear™ Pad to adapt to the head for approximately 5 to 10 minutes before testing.

## Hearing Mentor

This function 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.
The bilateral linking function can be used to make changes simultaneously on both sides when two sound processors are programmed as a bilateral pair.
Click the Recalculate button if you need to return to the initial prescription for the patient's sound processor. Click the Feedback Analyser 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, Noise reduction or Impulse noise reduction. Directionality, Bilateral directionality, and Noise reduction will be directed by SmartSound®iQ. In the program settings, you can also select a different prescription model than CBP.

### 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 of beep alerts in the processor.

### Wireless setup

How to pair wireless devices to the sound processor:

1. Go to the Fitting/Wireless Setup tab.
2. See paired devices, follow the on-screen instructions to pair and unpair.
3. See Volume balance settings, follow the on-screen instructions to adjust settings.

The serial number of the paired wireless device can be added. To change the serial number, click on the existing one to edit. To unpair the wireless device, follow the on-screen instructions.

**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.

## Finalise

The Finalise tab contains the sub-selections Save and Session Report.

## Save

The Save tab 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 stand-alone mode).

**Note:**
If you are using stand-alone 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 customisable report with one section intended for the patient and one section intended for the clinician. The clinician may select and deselect which sections shall be included in the respective sections before printing it.

## Serious incidents

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

When contacting your Cochlear representative, you may be asked to create a log file of the issue you are experiencing. This is done in the following way:

1. Go to the settings menu and click Debug.
2. Go to Change logging level and choose Advanced. Decide if you would like to share additional data about your computer, relevant to resolve the issue, by selecting that option as well.
3. Click Apply.
4. Repeat the steps you took when the issue first occured.
5. Save the log file.
6. The next time you log in the logging level will be reset to default.

### Troubleshooting

- The antivirus software should be updated with the latest antivirus definition.
- If there are issues starting or running the software, consider excluding the following processes from real time scanning:

    - BahaFittingSoftwarex.x.exe
    - CefSharp.BrowserSubprocess.exe

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 |
| cochlear.com/manuals | Consult instructions for use | UDI | Unique device identifier |
| REF | Catalogue number | YYYY-MM-DD | Manufacturer and date of manufacture |
| | Caution | | |

## Trademark legal notice

# Notes

# Notes

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