

# Aura:fit Relate 5.8

## User Guide



Aura:fit Relate 5.8 fitting software will henceforth be referred to as “Aura:fit Relate” or “the fitting software” or “fitting software.”

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## Structure and Navigation

The navigation of the fitting software generally flows from top to bottom and left to right.

### Main Menu Options

|                            |                                                                                 |                                                                           |
|----------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| File.....                  | Import Client<br>Export Client<br>Print<br>Software Updates                     | Save<br>Close Session<br>Close Aura:fit Relate                            |
| Forms.....                 | Repair Form<br>Remake Form<br>Loss & Damage Form                                |                                                                           |
| Hearing<br>Instrument..... | Save<br>Test Mode<br>Verification Mode<br>HI Update<br>HI Repair / Reset        | Stock Mode<br>Transfer Fitting<br>Delete Wireless Pairing                 |
| Options.....               | Preferences<br>iCube Configuration                                              | Accessory Firmware Update<br>Change uDirect 2 Language Pack               |
| Help.....                  | User Guide<br>Trial Device Cleaning Guide<br>Create Training Session<br>Support | FDA Software Labeling (USA only)<br>About DSL v5<br>About Aura:fit Relate |

### Toolbar

The toolbar is located at the top right corner of the application. The icon functionality is as follows:



### Quick View Pane

Located in the top right corner, the Quick View Pane displays information about the status of the hearing instrument fitting. Each tab contains additional information about a specific section and can expand by clicking on the plus sign.

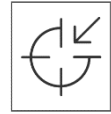
|                                                                                     |                        |                                                                                                |
|-------------------------------------------------------------------------------------|------------------------|------------------------------------------------------------------------------------------------|
|  | <b>Client tab</b>      | Overview of key client information                                                             |
|  | <b>Connection tab</b>  | Connection status of hearing instrument(s)                                                     |
|  | <b>Alerts tab</b>      | Lists all help and alert messages that have occurred during the current fitting                |
|  | <b>Client View tab</b> | Allows display of client-oriented screens on a second monitor while using the fitting software |

## myUnitron Setup

Located left of the Tool Bar on the main menu, is a link allowing you to sign-in to your myUnitron account. Once you have signed in, your username will be displayed. Click it to sign out (your username will be remembered).

## Recalculate

Click the Recalculate button in the upper right of the screen to see all the pending changes and the recalculation options. It will recalculate the fitting based on data, such as the current audiogram, fitting formula, and hearing instrument acoustics. The default recalculation options vary depending on the pending changes.



The Recalculate button will be highlighted when a recalculation is recommended during fitting.

## Mute / Unmute

Indicates the current state of the hearing instrument(s): muted or unmuted. Mute / Unmute can be selected

individually for each device or binaurally by clicking the center of the button. The center of the button also displays the currently active environment for the hearing instrument(s).



## Fitting Mode

The fitting mode can be changed by clicking on the button and selecting the desired setting from the dropdown box. When client information is entered and the age is 18 years or less, the fitting software will automatically prompt you to select the appropriate fitting mode option via a pop-up window.

Fitting mode defaults can be edited under **Options > Preferences > Fitting Session > Pediatric Modes**.

# Preparing the Hearing Instruments

## Noahlink™ Wireless / Noahlink™ Wireless 2

Switch the hearing instrument(s) on by inserting batteries and closing the battery doors or, if the hearing instrument(s) are rechargeable, press and hold the lower part of the button on each of the hearing instrument(s) for 3 seconds until the indicator light changes to solid green. This will also place the units in pairing mode, which lasts for 3 minutes.

If connecting to hearing instrument(s) that are not saved in the current session, the hearing instrument(s) must be in pairing mode. If connecting to hearing instrument(s) that are already saved in the current session, the hearing instrument(s) do not need to be in pairing mode.

## NOAHlink™ / HI-PRO®

BTE/RIC: Open the battery door and insert the programming cable into the programming port. Connect the other end of the cable to the NOAHlink or HI-PRO (initially fit to a 40 dB HL flat hearing loss configured for the left ear).

ITE: Remove the battery door and insert the programming cable. Connect the other end of the cable to the NOAHlink or HI-PRO.

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## iCube II

When using iCube II for the first time, you will need to configure the fitting device. Select **Options > iCube Configuration** and follow the on-screen instructions. Insert batteries into the hearing instrument(s) and close the battery door. Either place the hearing instrument(s) inside the iCube II neck loop on a desk or place the iCube II around your client's neck and place the hearing instrument(s) on your client's ears.

## Client Menu

### Information

This screen shows the Client Summary, Session Summary and Accessories.

### Audiogram

Click on the graph to add thresholds to the audiogram, or right click for additional options. The transducer for audiometry can be selected from the dropdown menu. Additionally, measured Tinnitus Match information can be entered at the bottom of the Audiogram screen.

### RECD

This screen provides the option to enter real-ear-to-coupler difference (RECD) values or import them if they already exist. If RECD values have not been measured, age-appropriate average values generated by the selected fitting formula will be used. Click the **Enter RECD** button to enter RECD values.

### REUG

This screen provides the option to enter real-ear unaided gain (REUG) values or import them if they already exist. If REUG values have not been measured, age-appropriate average values generated by the selected fitting formula will be used. To complete the REUG screen, enter the data for the appropriate ear by clicking on the graph. Right clicking on the graph also provides the option to edit points. Select **Use Entered** to use the REUG data entered in the graph for fitting formula targets or **Use Average** to use age appropriate average REUG values.

## Instruments Menu

### Selection

The Selection screen provides the option to detect or simulate hearing instrument(s). To detect:

1. Choose the desired programming interface from the drop-down menu.
2. Click the Detect button to perform a detection. Ensure the hearing instrument(s) are prepared for detection according to the 'Preparing the hearing instruments section' of this guide.
3. In cases where the data in the hearing instrument differs from that stored in the fitting software, follow the prompts to select which fitting you would like to use.

## First Fit

The First Fit workflow is optionally displayed when:

- A new client is being fitted for the first time with new hearing instrument(s)
- You select to Create New Fitting at the end of the Detect sequence.

When the workflow is launched, there are up to five steps you can navigate through.

1. **Confirm technology level (Trial devices only):** View the differences in features between the current and other available technology levels. Click **Next** to maintain the current level. If you want to make a change, clicking **Apply** will launch the Change Technology Level workflow.
2. **Confirm client information:** Review the client's date of birth, audiogram, and experience with hearing instrument(s), i.e. First Time or Long Term. If you need to change the date of birth or the audiogram information, select **Cancel** to make those changes. This will disconnect the hearing instrument(s) and following a subsequent **Detect**, the First Fit workflow will be launched again.
3. **Confirm device acoustics:** Confirm the device acoustic settings and change values, if necessary.
4. **Confirm First Fit:** First Fit has been calculated and the hearing instrument(s) will automatically be unmuted (the option exists to manually mute again). You have the option to select the Fitting Formula, adjust the Adaptation Manager and launch the Feedback Optimization workflow.
5. **First Fit complete:** Provides quick links to the most common follow-on actions within the fitting software.

## Technology Change

This screen provides access to Upgrade functionality. Clicking on one of the technology level buttons will launch the Change Technology Level workflow. Follow the on-screen instructions to change the technology level of the connected hearing instrument(s). The workflow will provide the following options:

- **Transfer fitting:** Transfers the program structure, frequency response, acoustics, Automatic Adaptation Manager status and accessories in the current client session to the hearing instrument(s).
- **Create new fitting:** Resets the hearing instrument(s) to the recommended defaults. Select your desired option and continue through the steps in the workflow.

The data logging in the hearing instrument(s) will be lost during this process.

## Acoustics

Configure items such as: coupling, venting, earhook, tubing, ear piece, and receiver type.

### BTE and RIC hearing instrument(s)

- If you have ordered an earmold or cShell with an IntelliVent, enter the code and the fitting software will automatically use the optimal venting
- For BTEs select Regular Tube, Slim Tube or Power Slim Tube (if applicable):
  - For BTEs with Regular Tube (an Earhook), select Ear Piece and Vent size.
  - For BTEs with Slim Tube or Power Slim Tube, select Ear Piece, Vent size and Tubing Length.

- For RICs select Receiver, Ear Piece, Wire Length (optional) and Dome Size (optional)
  - With some products, the fitting software automatically detects the receiver during the detection process. Press the Check button to manually check that the fitted receiver matches the one you have selected in the fitting software.

### Custom hearing instrument(s)

For custom hearing instruments, you can configure the vent. If you have ordered the custom products with IntelliVent, the fitting software will automatically read the code and use the optimal venting. With simulated fittings, you can select the shell and receiver type.

### Accessories

This screen displays accessories which are compatible with the fitted hearing instrument(s). Select the accessory and click on the **include in fitting** button to include the accessory in the fitting.

### Pre-Fitting

|                                              |                                                                                                                                                                                                |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Super / Ultra Power pre-sets (if applicable) | Classic: little to no signal processing and no directionality.<br>Conventional: moderate signal processing and some directionality.<br>Current: advanced signal processing and directionality. |
| Fitting Formula                              | Select your desired fitting formula: DSL v5 Adult, DSL v5 Pediatric, NAL-NL1, NAL-NL2, and NAL-NL2 Tonal Language.                                                                             |
| Processing Strategy                          | With DSL v5 Adult or DSL v5 Pediatric, select your desired processing strategy: WDRC or Linear. Selecting the other fitting formulas provides the WDRC processing option only.                 |
| Tinnitus Masker Strategy                     | Select your desired tinnitus masker signal strategy. The tinnitus masker noise can be viewed and adjusted in the <b>Fitting &gt; Tuning &gt; Tinnitus Masker</b> toolbox.                      |
| Frequency Compression Strategy               | Select whether to calculate the frequency compression strategy independently for the left and right hearing instruments.                                                                       |

### In Situ

Use the In Situ screen to assess hearing sensitivity and uncomfortable loudness levels via signals generated by the hearing instrument(s). The In Situ measurement results can be used to define the fitting formula targets.

Click on the **Start In Situ** button for the ear you would like to assess. Follow the In Situ workflow to progress through the test.

## Fitting Menu

### Tuning

On the Tuning screen, All Programs is always selected by default; this ensures that the relative differences across all programs are maintained when making changes.

Settings can be adjusted by clicking on the applicable toolbox.

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Adaptation Manager           | The Automatic Adaptation Manager is activated when the check box is selected. The fitting software uses a proprietary calculation to determine the starting adaptation manager setting and the adaptation rate for the fitting.                                                                                                                                                                                                                                |
| Occlusion Manager            | Select the desired occlusion setting to address any occlusion related complaints. This feature impacts all programs except the music program by default. Select the checkbox to enable the occlusion manager for music programs.                                                                                                                                                                                                                               |
| Bass Enhancer (if available) | Select the desired setting to increase low frequency gain and MPO (emphasis below ~ 1 kHz).                                                                                                                                                                                                                                                                                                                                                                    |
| Soft / Mod / Loud Controls   | Select the frequency region(s) and input level to be modified. A range of fitting values can be selected by either choosing a specific input, channel grouping, or selecting <b>All</b> . To select multiple frequency regions for adjustment, you can click and drag across the table. The scroll bar along the bottom of the table allows you to view frequency regions that are outside the visible area.                                                   |
| MPO / Gain / CR Controls     | Select the frequency region(s) and parameter type to be modified. If available, TK soft speech can be used to adjust the gain for low level sounds (this feature must be enabled in preferences before it can be adjusted). To select multiple frequency regions for adjustment, you can click and drag across the table. The scroll bar along the bottom of the table allows you to view frequency regions that are outside the visible area.                 |
| App Equalizer                | In follow up fittings, selecting a program will show the settings the client has applied to that program via the app.                                                                                                                                                                                                                                                                                                                                          |
| Frequency Compression        | Click the <b>Enable Frequency Compression</b> checkbox to activate this feature. Depending on the product, you can adjust the frequency compression to the desired setting using the More or Less buttons or by adjusting the Audibility / Distinction and Consonant Clarity / Vowel Quality sliders.                                                                                                                                                          |
| Fitting Advice               | Select a specific situation and concern for recommended adjustments.                                                                                                                                                                                                                                                                                                                                                                                           |
| Tinnitus Masker              | Click the <b>Enable Tinnitus Masker</b> checkbox to enable this feature. Click the <b>Use client control to adjust noise level</b> checkbox to allow the client to adjust the tinnitus noise level using their hearing instrument controls. To select multiple frequency regions for adjustment, you can click and drag across the table. The scroll bar along the bottom of the table allows you to view frequency regions that are outside the visible area. |

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## Remote Adjust

Click **Start a Remote Adjust session** to launch the Remote Adjust workflow. You can also view the gain offset values for each of the changes supported by the hearing instrument(s). These values are read only.

## Configure Features

Select the Configure Features screen to adjust adaptive parameters in the hearing instrument(s). Select the program(s) to view and alter the values of the adaptive parameters.

## Program Manager

This screen allows you to add or remove manual programs, copy programs, rename programs, change program order, and assign easy-t / easy-DAI access (when applicable). To add a program manually, click the arrow next to the appropriate program in the Available Programs section.

## Feedback Optimization

Select the Feedback Optimization screen to run the feedback test. In cases where the environment may have impacted the test (e.g., excess noise present), the results include a combination of measured values and predicted feedback threshold values; the status then indicates Incomplete. Repeating the test will replace any predicted values with measured values if they can be reliably obtained in the current test environment. Once the feedback test is complete, the hearing instrument's gain is limited as shown on the graph where:

- Black line = feedback threshold
- Grey line = hearing instrument gain limit
- Green line = target gain for 50 dB pure tone input
- Red or Blue line = aided gain for 50 dB pure tone input

## Automatic REM

Automatic REM is an automated guidance system for real ear measurements (REM). It guides you through a step-by-step workflow of probe tube placement, obtaining real ear measurements, and automatic target matching.

Automatic REM is available when using the fitting software within Noah.

Click [R] / [Start both] / [L] to start Automatic REM. The workflow will then guide you through a series of steps.

## End Fitting Menu

### HI Setup

Select the HI Setup screen to configure the function of the user controls on the hearing instrument(s). In addition, HI Setup provides access to other device parameters via toolboxes along the bottom of the screen:

|                                  |                                                                                                                                                                                                     |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Bluetooth</b>                 | Edit the name of the hearing instrument(s) as seen by other Bluetooth devices, enable/disable Adaptive Bandwidth, and select the primary ear used for Bluetooth.                                    |
| <b>TV Connector</b>              | Configure how the hearing instrument(s) will behave when they come into range of a TV Connector.                                                                                                    |
| <b>Volume Settings</b>           | Choose the desired step size of volume control increase / decrease.                                                                                                                                 |
| <b>Startup Settings</b>          | Select the desired Startup Program and Startup Delay. Enable / disable the automatic behavior to turn on rechargeable hearing instrument(s) when they are removed from the charger (if applicable). |
| <b>Data Logging</b>              | Select the desired data logging behavior.                                                                                                                                                           |
| <b>Program Toggle Exceptions</b> | Select any programs to be excluded from the toggle sequence.                                                                                                                                        |
| <b>Tap Control Sensitivity</b>   | If applicable, configure how firmly the client needs to tap on their hearing instrument(s) to activate the tap control.                                                                             |

## Beeps

Demonstrate and configure user notification beeps in the hearing instrument(s).

|                                       |                                                                                                             |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Beep Setup</b>                     | Select the intensity and frequency of the beeps for each ear.                                               |
| <b>Beep Enabling</b>                  | Deselect beep notification types to deactivate them for the client.                                         |
| <b>Trial Duration (if applicable)</b> | Shows the amount of time before the 'End of trial period' beeps are generated in the hearing instrument(s). |

## Digital Solutions Setup

The Digital Solutions Setup screen provides an easy way to enable insights for you and your clients. The first steps are one time only activities to Sign in / Create your account and to enable Digital Solutions.

Following detection, hearing instrument(s) automatically allow Digital Solutions activation. Once you have saved to the hearing instrument(s), the client can complete the setup process by selecting to 'Activate' Digital Solutions when setting up their **Hearing Remote app** (available for Bluetooth enabled hearing instruments). The next time you open a session for that client, you will see confirmation that activation is complete, enabling **Remote Adjust** and **Tutor**. Your client has the ability to manage their insights settings and opt-out of individual features via the app. You can see their preferences by going to **End Fitting > Digital Solutions > Client Settings**.

## Fitting Summary

The Fitting Summary screen provides an overview of primary fitting-related items for the hearing instrument(s). The table provides an opportunity for a final check of the fitting settings and general status prior to ending the session. If desired, additional details can be viewed by clicking the **More Info** button.

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This screen also includes options to **Send Email** (auto-generates a getting started email of support materials for the client), **Print**, **Save**, or **Close Session**.

## Data Logging Menu

### Overview

This screen provides a high-level view of the client's usage and listening lifestyle. The left-hand pane of the screen shows **History** (allows you to view the history from previous sessions), **Quick Links** (buttons linking to commonly used features in follow up fittings), and **Difficult Situation Predictions** (prediction of difficult 'sound types' that your client may be likely to experience).

### Data Logging

This screen provides insights into how the client interacts with the hearing instrument(s). A graph in the centre of the screen shows the percentage of time spent in automatic and manual programs. The table provides information related to average usage and volume control adjustments across all programs. This screen also displays the history from previous sessions, duration of client usage.

### Capture All

This screen provides an overview of a client's listening lifestyle. All the time spent in acoustic real-world listening situations is classified by the hearing instrument(s) and mapped to the defined listening environments.

|                             |                                                                                                                                                                                                                                                                   |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| History                     | View Capture All history from previous sessions.                                                                                                                                                                                                                  |
| Technology Level Comparison | Displays the current technology level and alternate levels available.                                                                                                                                                                                             |
| Coverage Screen             | Shows data from the hearing instrument(s) on how well a technology level is optimized for the listening environments where the client spends their time. The boxes below the bars show the percentage of time the client has spent in each listening environment. |
| Performance Screen          | Performance shows how often speech is detected from different directions and how effectively it is managed. This screen also displays maximum mic mode settings for each technology level.                                                                        |
| Feature List                | Displays the Feature Comparison dialog, allowing you to see a side-by-side comparison of the features.                                                                                                                                                            |

## Curve Display Options

All the curves displayed in the fitting software, aside from the Feedback Optimization graph, are based on targets that are generated assuming a speech input. On any screen displaying a graph, change the

display by clicking the curve display icon above the upper right graph. Adjustments made here are applied to both the left and right graphs.

Depending on the section of the fitting software, there are different options available for selection.

## Main Menu

Main Menu options are outlined in the Structure & Navigation section of this guide. Below are some details about a few of the menu items.

### Verification Mode

Verification Mode can be found under **Hearing Instrument > Verification Mode**. This sets the hearing instrument into a verification mode to allow testing without the interference of adaptive features. There are 3 options:

- Adaptive features active
- Real Ear Verification
- 2cc Coupler Verification

### Transfer Fitting

The Transfer Fitting workflow can be accessed through **Hearing Instrument > Transfer Fitting**. Transfer Fitting assists with the transfer of a fitting to or from another hearing instrument.

### Create Training Session

Training Mode is used to demonstrate the full functionality of each screen as if hearing instruments were connected. Training Sessions can be accessed on the Main Menu under **Help > Create Training Session**.

Select a client and then create a training session. You can simulate the entire workflow of detecting hearing instruments as well as tests such as the Feedback Optimization test. You can also simulate data logging information including Capture All, if applicable. Training Sessions cannot be saved.

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## Important Safety Information

Aura:fit Relate fitting software is a medical device. As such, the use of this product carries some risk of harm and so it is important that only properly qualified hearing care professionals (HCPs) use Aura:fit Relate fitting software in accordance with this user guide and that they understand and heed the warnings contained herein.

### **Intended use:**

The fitting software is the standalone software which is intended to be used by qualified hearing care professionals to configure, program, and fit hearing aids to the intended person's specific requirements.

This user guide provides a detailed introduction to hearing instrument fitting with Aura:fit Relate. An electronic version can be obtained on [unitron.com/aurafit-relate-instructions](https://unitron.com/aurafit-relate-instructions).

### **Intended user:**

The fitting software is intended for qualified hearing care professionals.

### **Intended patient population:**

The fitting software is intended for patients with unilateral and bilateral, mild to profound hearing loss or in combination with chronic tinnitus, who require the fitting of a hearing aid. The tinnitus masker feature is intended for patients from 18 years of age and above.

### **Indications:**

Indications are not derived from the fitting software, but from compatible hearing aids. General clinical indications for the use of hearing aids and tinnitus masker are:

- Presence of a hearing loss
  - Unilateral or bilateral
  - Conductive, sensorineural, or mixed
  - Mild to profound
- Presence of chronic tinnitus (only for hearing aids which offer tinnitus masker)

### **Contraindications:**

Please note, contraindications are not derived from the fitting software, but from compatible hearing aids. General clinical contraindications for the use of hearing aids and tinnitus masker are:

- Hearing loss is not in the fitting range of the hearing aid (i.e., gain, frequency response)
- Acute tinnitus
- Deformity of the ear (i.e., closed ear canal, absence of the auricle)
- Neural hearing loss (retro-cochlear pathologies such as absent/non-viable auditory nerve)

The primary criteria for the referral of a patient for a medical or other specialist opinion and/or treatment are as follows:

- Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear in the previous 90 days
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days

- Acute or chronic dizziness
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal
- Pain or discomfort in the ear
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal
  - Perforated eardrum
  - Other abnormalities which the HCP believes are of medical concern

The HCP may decide that referral is not appropriate or in the best interests of the patient when the following applies:

- When there is sufficient evidence that the condition has been fully investigated by a medical specialist and any possible treatment has been provided.
- The condition has not worsened or changed significantly since the previous investigation and/or treatment
- If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend appropriate hearing aid systems subject to the following considerations:
  - The recommendation will not have any adverse effects on the patient's health or general wellbeing
  - The records confirm that all necessary considerations about the patient's best interests have been made. If legally required, the patient has signed a disclaimer to confirm that the referral advice has not been accepted and that it is an informed decision.

#### Limit of use:

Aura:fit Relate fitting software usage is limited to fit and adjust compatible devices. Aura:fit Relate fitting software is not intended for any diagnostic purpose.

#### Compatible hearing aids:

| Platform              | Form Factors              |
|-----------------------|---------------------------|
| Relate                | All released form factors |
| Relate <sup>2.0</sup> | All released form factors |
| Relate <sup>3.0</sup> | All released form factors |
| Relate <sup>3.1</sup> | All released form factors |
| Relate <sup>4.0</sup> | All released form factors |
| Relate <sup>5.0</sup> | All released form factors |

#### Side effects:

Please note, side effects are not derived from the fitting software, but from compatible hearing aids.

Physiological side effects of hearing aids, such as tinnitus, dizziness, cerumen build up, too much pressure, sweating or moisture, blisters, itching and/or rashes, plugged or fullness and their consequences like headache and/or ear pain, may be resolved or reduced by your hearing care professional. Conventional hearing aids have the potential to expose patients to higher levels of sound exposure, which might result in threshold shifts in the frequency range affected by acoustic trauma.

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### **Clinical benefit:**

The benefit for the patient is that the fitting software provides the capability to set the hearing aid setting to individual needs and to store them to the hearing aid. The benefit for the hearing care professional is related to patient management.

### **Risks:**

In the case of this fitting software, these risks manifest themselves through the hearing aids it is intended to program. That is, the fitting software itself cannot directly harm either the user (HCP) or the wearer of the hearing aids but its use (or misuse) can result in:

- wrongly programmed hearing aids being dispensed to patients, and/or
- harmfully loud sounds being delivered via hearing aids to patients during fitting sessions / demonstration sessions.

These risks are extremely low, but both HCPs and wearers of hearing aids should be aware of them, nonetheless.

Fitting Software informs about restrictions in the following cases:



#### **MPO**

MPO exceeds 132 dB.



#### **Fitting Session**

- Before a measurement/testing is performed.
- The acoustic parameters are selected.
- Before test signals are produced.



#### **Tinnitus**

- The output level of the Tinnitus Masker is above 80 dB(A).
- The tinnitus balance is selected for a patient below age of 18.



#### **Sound Pressure Level**

MPO exceeds 100 dB SPL while using In Situ.



#### **Data Transmission**

Fitting data are transferred to the hearing instrument.



#### **Intended patient population**

Device is fitted to patient population aged  $\leq 36$  months.

# Compliance Information and Descriptions of Symbols

## Compliance information

Europe: Declaration of Conformity

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745.

The user guide is accessible via the **Help** function within the fitting software. The user guide for all fitting software versions in all applicable languages in electronic form is accessible via webpage:

<https://www.unitron.com/aurafit-relate-instructions>

To obtain a free paper copy of the instructions of use, please contact your local manufacturer representative. A copy will be sent within 7 days.

Any serious incident that has occurred in relation to this product, should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident that directly or indirectly led, might have led, or might lead to any of the following:

- the death of a patient, user, or other person
- the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health
- a serious public health threat

## Security notice

Patient data is private data, and its protection is important:

- Make sure your operating system is up to date
- Make sure your installed fitting software version is up to date
- Have the Windows user login activated, use strong passwords, and keep credentials secret
- Use adequate and up-to-date malware and antivirus protection

Depending on national laws, you might be required to encrypt all patient data in order not to be held liable in case of data loss and/or theft. You can use drive encryption (e.g., the free Microsoft BitLocker) to protect all data on your PC. If working under Noah, consider using the Noah database encryption.

Make sure to keep data safe at all times. Please be aware that this listing is not exhaustive.

- When transferring data through unsafe channels, either send anonymous data or encrypt it.
- Protect data backups not only from data loss but also from theft.
- Remove all data from data medium which are no longer used or will be disposed.

## Software maintenance

We are constantly monitoring feedback from the market. If you experience any issues with the latest fitting software version, please contact your local manufacturer representative.

## Descriptions of symbols

|                                                                                                          |                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                         | <p>With the CE symbol, Sonova AG confirms that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation.</p> |
| <br>Name, address, date | <p>Combined symbol “medical device manufacturer” and “date of manufacture” as defined in in EU Regulation (EU) 2017/745.</p>                                                                                                                                                       |
|                         | <p>Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union.</p>                                                                                                                                                   |
|                         | <p>Indicates that the device is a medical device.</p>                                                                                                                                                                                                                              |
|                         | <p>Indicates the manufacturer’s catalogue number so that the medical device can be identified.</p>                                                                                                                                                                                 |
|                         | <p>An indication that electronic instructions for use are available.</p>                                                                                                                                                                                                           |
|                         | <p>This symbol indicates that it is important for the user to read and take into account the relevant information in these user guides.</p>                                                                                                                                        |
|                        | <p>Provides further clarification about a feature or functionality.</p>                                                                                                                                                                                                            |
|                       | <p>Indicates a restriction in functionality or highlights important information that requires your attention.</p>                                                                                                                                                                  |
|                       | <p>Indicates that something went wrong and requires correction in order to continue.</p>                                                                                                                                                                                           |
|                       | <p>HIMSA certification seal NOAHSEAL.</p>                                                                                                                                                                                                                                          |

## System requirements

|                                      |                                                                                                                                                                                                                                                                                                   |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operating system                     | <ul style="list-style-type: none"> <li>Windows 11, Home / Pro / Enterprise / Education</li> <li>Windows 10, Home / Pro / Enterprise / Education</li> </ul>                                                                                                                                        |
| Processor                            | Intel Core or higher performance                                                                                                                                                                                                                                                                  |
| RAM                                  | 8 GB or more                                                                                                                                                                                                                                                                                      |
| Hard disk space                      | 4 GB or more                                                                                                                                                                                                                                                                                      |
| Screen resolution                    | 1280 x 1024 pixels                                                                                                                                                                                                                                                                                |
| Patient secondary display resolution | 1366 x 768 pixels                                                                                                                                                                                                                                                                                 |
| Graphic card                         | 16 million (24bit) screen colors or more                                                                                                                                                                                                                                                          |
| Serial COM port                      | One for HI-PRO if used via serial COM port                                                                                                                                                                                                                                                        |
| USB ports                            | <ul style="list-style-type: none"> <li>Bluetooth adaptor</li> </ul>                                                                                                                                                                                                                               |
| One for each purpose                 | <ul style="list-style-type: none"> <li>Accessory programming</li> <li>HI-PRO USB / HI-PRO 2 / iCube II / Noahlink Wireless / Noahlink Wireless 2</li> </ul>                                                                                                                                       |
| Programming interfaces               | <ul style="list-style-type: none"> <li>iCube II</li> <li>NOAHlink / Noahlink Wireless / Noahlink Wireless 2</li> <li>HI-PRO / HI-PRO USB / HI-PRO 2</li> </ul>                                                                                                                                    |
| Noahlink driver                      | Latest version available                                                                                                                                                                                                                                                                          |
| Noahlink Wireless driver             | Latest version available                                                                                                                                                                                                                                                                          |
| Internet connection                  | Highly recommended                                                                                                                                                                                                                                                                                |
| Sound card                           | Stereo                                                                                                                                                                                                                                                                                            |
| Playback system                      | 20 Hz – 14 kHz                                                                                                                                                                                                                                                                                    |
| NOAH version                         | <p>Latest version (NOAH 4.4.2280 or higher)</p> <p>Please check the NOAH limitations for Windows operating systems on <a href="http://www.himsa.com">http://www.himsa.com</a></p>                                                                                                                 |
| Automatic REM                        | <p>Noah Version 4.4.2280 or higher</p> <p>Natus® Otosuite version 4.81-4.96</p> <p>Auditdata Primus version 4.1-4.5</p> <p>Auditdata Measure version 6.0-6.5</p> <p>Interacoustics Affinity Suite version 2.19-2.27</p> <p>Signia Unity version 5.9-6.5</p> <p>MedRX Studio version 1.2.1-1.5</p> |

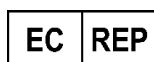
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058-5267-058  
Aura:fit Relate 5.8



This user guide is applicable for Aura:fit Relate 5.8 and later subversions of Aura:fit Relate 5.8 fitting software. For previous versions of the fitting software user guide please contact your local representative.