

# Phonak

# Target 8.1

## Phonak Target User Guide



### Intended use:

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

This user guide provides a detailed introduction to hearing aid fitting with Phonak Target. An electronic version can be obtained on [phonakpro.com](http://phonakpro.com) on the Phonak Target Support page. In addition, you can find [News] in the Phonak Target start screen.

### Intended user:

Qualified hearing care professionals.

### Intended patient population:

The 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. Tinnitus Balance is intended for patients from 18 years of age and above.

### Indications:

Please note, indications are not derived from the fitting software, but from compatible hearing aids. General clinical indications for the use of hearing aids and Tinnitus Balance 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 Balance)

### 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 Balance 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:**

Phonak Target usage is limited to fit and adjust of compatible devices. Target is not intended for any diagnostic purpose.

**Compatible hearing aids:**

| Platform | Form Factors              |
|----------|---------------------------|
| Lumity   | All released form factors |
| Paradise | All released form factors |
| Marvel   | All released form factors |
| Belong   | All released form factors |
| Venture  | All released form factors |
| Quest    | All released form factors |
| Spice+   | All released form factors |
| Spice    | All released form factors |
| Lyric    | 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.

**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.

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## Structure and navigation

The three tabs [Patient], [Instruments] and [Fitting], as well as the dashboard above offer you easy navigation and status information.

You can hover on each of the icons in the dashboard to see key information such as creation date of the audiogram, serial numbers of the hearing aids, fitting formula, feedback test status, Bluetooth® side, and more.

| Client  | Instruments  | Fitting   |
|---|--|---|
| All patient information, such as personal data, audiogram, RECD, and REUG are found within [Patient]. | Hearing aids, acoustic parameters, and accessories are found within [Instruments]. | All hearing aid adjustments and fine tuning can be done within [Fitting]. |

## Preparation of the hearing aids and CROS

### iCube II or Noahlink Wireless™

No cables to the hearing aids or CROS are needed. Just insert the battery and turn on the hearing aid or CROS by closing the battery compartment. For rechargeable, turn on the hearing aid or CROS.

### NOAHlink™ or HI-PRO®

Connect the programming cables to the hearing aid or CROS and the fitting device. Please use Phonak labeled cables.

### Phonak Trial™ hearing aids

Phonak Trial hearing aids are offered as BTE and RIC hearing aids with direct connectivity. Phonak trial hearing aids offer the ability to change performance levels in one device

In the bottom black menu bar, click [Trial & tools]. Select [Trial hearing aids] and [Configure]. Select the desired performance level and press [Continue]. Once the process is complete, the devices are ready to be fit in a fitting session.

## Junior mode

Depending on the age of the child, Junior mode offers age specific DSL or NAL defaults and hearing aid configurations optimized to meet the needs of children and their families. Junior Mode includes four age ranges:

- 0-3 years
- 4-8 years
- 9-12 years
- 13-18 years

These default settings are endorsed by the Phonak Pediatric Advisory Board and National Acoustics Laboratory. They provide a starting point for flexible and efficient pediatric fittings. Within [Setup], you can customize and change the Junior mode default parameters to better suit your pediatric fitting workflow.

Entering the date of birth will automatically trigger a Junior mode fitting prompt for children between the ages 0-18 years after opening a new patient session. You can manually change the appropriate age range in the dropdown menu for the child if you believe the behavioral/physical age is different from the chronological default age. Click [Apply Junior mode] to continue.

A notification to attach a tamperproof solution will appear for children between 0–3 years when hearing aids are initially connected. If the available hearing aid does not have a tamperproof solution, a different notification will appear.

## Transfer fitting

Target lets you transfer settings from a fitting session to a new selection of hearing aids. The transfer fitting tool can be found within the [Fitting] drop down menu, located in the top black menu bar. During the transfer process, Target will prompt you about which settings can or cannot be transferred.

Transferring a fitting is not possible to or from a bimodal fitting.

## Connect the hearing aids

Within the patient's fitting session confirm that the correct fitting device is shown. To change the fitting device, use the pull down arrow next to the fitting device in the dashboard.

Click [Connect] to start the fitting. The connected hearing aids will appear in the dashboard. Devices available for pairing will automatically appear.

If a device is not found, open/close the battery door or turn off/on the rechargeable hearing aids to initiate pairing mode.

Press the multifunction button on the hearing aid to highlight it in the list when multiple devices are available or to confirm the side to assign to a patient.

The audiogram data from Noah™ will be automatically imported into Phonak Target and taken into account for the pre-calculation. In a standalone version of Target, enter the audiogram in the [Audiogram] screen.

## Receiver check and acoustic parameters

In [Instruments] > [Acoustic parameters], enter or confirm the correct coupling information.

If the patient has a custom earpiece manufactured by Phonak, the acoustic code on the earpiece can be entered. The acoustic code is a six digit code printed on the earpiece.

The attached receiver fitted onto the hearing aid is automatically checked against what is selected in Target when hearing aids are connected. This check can also be done by clicking [Check] in the acoustic parameters screen. If there is a mismatch, it is possible for you to rectify the mismatch either in the acoustic parameters screen or by replacing the receiver to match what is entered in Target.

## Accessories

Accessories can be manually selected in [Instruments] > [Accessories]. Check [Show only compatible accessories] to only see the list of accessories that are compatible with the selected hearing aids.

## Feedback & real ear test

Click on [Fitting] to access [Feedback & real ear test]. The feedback test can be run in both ears, or one ear at a time. Click [R] / [Start both] / [L] to start the test.

## AudiogramDirect

AudiogramDirect is an in-situ hearing test within Phonak Target. You can test patients' hearing directly through their hearing aids. AudiogramDirect does not replace diagnostic audiological assessments.

To change the default AC and UCL measurement behavior, go to [Setup] > [Fitting session] > [AudiogramDirect].

Click [AudiogramDirect] > [Start] to test air conduction (AC) hearing thresholds and uncomfortable loudness levels (UCLs) using the connected hearing aids. UCL measurements are optional and they are disabled during a Phonak Remote Support session.

## Global tuning

Go to [Global tuning] > [Initial fitting] if adjustments to the gain level, occlusion compensation, or compression are required. The gain level and compression settings are based on the patient's usage experience and the selected fitting formula.

Depending on the connected hearing aids, additional tools such as [Tinnitus Balance] and [CROS Balance] can be accessed via the tab in the lower part of the screen. To adjust the loudness ratio between the CROS device and the hearing aid, click on [CROS Balance].

### Auto acclimatization

Automatically acclimatize a patient to a higher overall gain level by setting a target gain level you wish the hearing aid to reach and the number of days the hearing aid would need to reach that target gain.

Select [Auto acclimatization] in the gain level menu in the [Initial fitting] tab. Specify the start level, the end level and the duration in which the gain of the hearing aid automatically increases to the set end level.

## TargetMatch

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

TargetMatch is available when using Target within Noah.

Click [R] / [Start both] / [L] to start TargetMatch. The assistant will then guide you through a series of step.

## Verification assistant

When performing verification outside of TargetMatch, the wide variety of signal processing schemes, gain and compression variables, frequency lowering, and noise management algorithms in hearing aids can impact the verification of the gain and MPO settings. To address these challenges, enable Verification assistant to turn off adaptive features for a streamlined verification process.

Verification assistant can be accessed via [Fine tuning] > [Gain & MPO] > [Verification assistant]. The assistant will then guide you through a series of steps.

## Fine tuning

Fine tuning gives access to more specific fitting functionalities such as adjusting gain and MPO, as well as hearing performance and sound cleaning features, for an individualized fitting.

The left side of the [Fine tuning] screen is used for the handling of the programs. The startup program, program structure, and streaming programs can be customized here.

Click [All programs] to adjust all programs simultaneously. Click [AutoSense OS] to modify all acoustic automatic programs or [AutoSense OS (streaming)] to modify AutoSense OS™ for streaming.

To modify a single program, click on the program, e.g. [Calm situation], in the list and adjust as needed.

Click on the [+] icon to add an additional manual program.

The undo or redo arrows are located next to [Fine tuning] and can be used to undo or redo steps in the fine tuning screen.

The gain values are adjustable for soft, moderate and loud input sounds, as well as MPO.

### Audibility fine tuning

Selectable sound samples and the related gain are shown in the curve display. The sound samples can be played to simulate a specific listening environment.

The gain values are displayed for soft, moderate and loud input sounds. Adjustments affect only gain levels and frequencies which are relevant to enhance the audibility of the selected stimuli, indicated by the different shades of red/right and blue/left.

### Automatic fine tuning

This is a situation-based fine tuning tool. The available adjustments are dependent on the patient's evaluation of the sound situation. Depending on the selected program, a recommended sound sample is pre-selected. The sound samples can be played to simulate the listening environment.

### Program options

Program options can be adjusted from the default settings. The features can be activated, deactivated, or changed in strength for each program individually. The available ranges within each scale are visible and depend upon performance level.

For direct connectivity hearing aids, the default switching behavior to access streaming can be modified for the TV Connector, Roger™, and PartnerMic™.

## SoundRecover2

SoundRecover2 is a frequency compression system with adaptive behavior.

SoundRecover2 is:

- On by default for flat or sloping hearing losses where the 8kHz threshold is 45 dB HL or poorer.
- Off by default for reverse sloping losses (8 kHz  $\geq$  30 dB better than 3 kHz).

To disable SoundRecover2, click on [Fine tuning] > [SoundRecover2]. Disable by unchecking the [Enable SoundRecover2] checkbox.

To fine tune SoundRecover2, click on [Fine Tuning] > [SoundRecover2].

- Slide toward [Audibility] to increase the ability to detect an /s/ and /sh/.
- Slide toward [Distinction] to increase the ability to distinguish the difference between /s/ and /sh/.
- Slide toward [Comfort] to increase the naturalness of sounds, such as male voices, own voice, or music.

## Tinnitus Balance

The Tinnitus Balance noise generator provides a means of sound enrichment that can be used as part of a tinnitus management program.

The noise generator can be enabled or disabled in [Fitting] > [Global tuning] > [Tinnitus Balance]. When enabled, the shape of the generated noise is shown in green. The curve display must be set to [Output].

The default characteristics are calculated based on the patient's audiogram. Within the drop down menu of [Tinnitus Balance shape], the default, [Set to hearing loss], can be changed to [Set to white noise] or [Set to pink noise].

The maximum output level of the Tinnitus Balance noise generator is limited to 85 dB(A). In accordance to common noise exposure recommendations, a warning message will be shown when the noise generator level exceeds 80 dB(A). If this occurs, the recommended maximum wearing time per day will appear below the maximum noise level.

More detailed adjustments to the Tinnitus Balance noise generator can be found in [Fine tuning] > [Tinnitus Balance].

Tinnitus Balance is not available in Phonak Sky™ hearing aids. Phonak does not have any recommended clinical fitting guidelines for fitting Tinnitus Balance to children under the age of 18.

## DataLogging

DataLogging can provide information about the listening environments the patient has been in and for how long. To access DataLogging information, go to [Fitting] > [DataLogging].



## Device options

By clicking [Device options] you can configure hearing aid options such as manual controls, signals and alerts, startup behavior or DataLogging.

When the hearing aid is connected, each configuration can be demonstrated on the hearing aid in [Signals & alerts].

With Phonak direct connectivity hearing aids, additional settings such as configuring the Bluetooth name, side and managing pairings can be found by clicking on [Bluetooth].

There is the option to email or print a customizable fitting report for the patient to take home. The report contains device information, as well as program information.

## Bimodal fitting

The Phonak Naída™ Link M can be used in bimodal fitting with an Advanced Bionics (AB) Naída™ CI M sound processor. The Phonak Sky™ Link M can be used in bimodal fitting with an AB Sky CI™ M sound processor.

Open the fitting session and confirm that the Noahlink Wireless is shown. Connect both the hearing aid and the sound processor to start the fitting. Devices available for pairing will automatically appear. Following connection of the hearing aid and the sound processor to the patient's fitting session, Target will automatically align the program structure and device options of the hearing aid to match the sound processor.

Proceed with using Phonak Target as you would in a standard fitting session to complete the fitting of the Naída Link M or Sky Link M hearing aid.

The sound processor is in read-only mode. No changes can be made or saved to the sound processor. You can view the sound processor settings and use the information to match the relevant settings on the hearing aid side.

The wireless connection between the hearing and the sound processor starts automatically once they are disconnected from the fitting session.

## Remote Support

Phonak Remote Support is designed to support the patient's fitting by providing hearing aid care from a distance.

### Requirements

- Latest Phonak Target software version available for optimal experience.
- Most current myPhonak app version installed on the patient's mobile phone.
- Advanced PhonakPro account activated with Remote Support. (Only applicable in certain countries.)
- An initial hearing aid fitting must be performed in the clinic.
- Computer with an integrated webcam or microphone or an external webcam and microphone connected to the computer. For better sound quality, use headphones with a microphone connection.
- Stable internet connection (Wi-Fi, LAN or 4G) with at least 5 Mbit/s of data transfer connection for uploads and downloads. Patients using 4G may incur additional charges for data usage depending upon their contract.

Internet connection can be checked within Target to ensure the setup is appropriate for a Remote Support session. Click on [Setup] > [Internet] > [Internet services] > [Connection test]. Once completed, the status will be shown.

## Set up for Remote Support

Select the patient for Remote Support. If there is more than one clinic site available, select the clinic where the remote session will take place.

Click on [PhonakPro login] to log into PhonakPro or to create a new PhonakPro account. A PhonakPro account is only applicable in certain countries.

An initial hearing aid fitting must be performed in the clinic. Upon clicking [Save & close session], Remote Support is enabled. To activate Remote Support in compatible hearing aids for an existing patient, the hearing aids must be connected to Target in the clinic. Upon saving the session, remote fitting is activated.


The patient must download the myPhonak app onto their smartphone and pair the hearing aids to the app before a Remote Support session can take place.

## Video call and follow up session

It is recommended that the patient has new batteries in their hearing aids or sufficient charge in their rechargeable hearing aids before connecting to the Remote Support session.

Click on [Start Remote Support]. You and your patient will be connected to the video call. You may have to wait for the patient to enter the Phonak Remote Support session with the myPhonak app.

Once connected, you will see and hear your patient. Make sure the video and microphone on your computer is enabled. Switching between an integrated or external microphone or webcam can be performed before or during a session by clicking on the settings wheel which is located at the top right hand corner of the Remote Support screen. As soon as the patient enters the Remote Support session and has accepted the camera and microphone requests on their smartphone, both videos are displayed on the screen.

The  icon is visible when you have established connection with the patient's hearing aids. Once the hearing aids are connected, use Target as you typically would in a follow-up session. The hearing aids are live and any adjustments you make are sent to the hearing aids in real-time.

It is not possible to end Phonak Remote Support with the patient until the fitting session in Target has been saved and closed. In the event that the connection between the patient's hearing aids and Target gets interrupted during an active Remote Support session, the hearing aids will reboot and keep the last valid fitting.

## Finishing the fitting session

You can close the session at any time by clicking [Save & close session] in the top right corner of the screen. Select the items to save. The save dialog will confirm the successful save of the hearing aids and accessories. After the save, Phonak Target will guide you to the start screen. If you are working under Noah, you can go back to Noah by clicking on [Back to NOAH] at the top right corner of the start screen.

## 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 full text of the Declaration of Conformity can be obtained from the manufacturer:

[www.phonak.com/us/en/certificates](http://www.phonak.com/us/en/certificates)

The user guide is accessible via the [Help] function within Phonak Target. The user guide for all Target versions in all applicable languages in electronic form is accessible via webpage:

<https://www.phonakpro.com/com/en/support/other-support/target-fitting-software/dfg-target.html>

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 Target 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 feedbacks from the market. If you experience any issues with the latest Target 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> |
|  <b>Name, address, date</b>   | <p>Combined symbol "medical device manufacturer" and "date of manufacture" as defined in in EU Regulation (EU) 2017/745</p>  |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;">EC</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 5px;">REP</div> | <p>Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union.</p>   |
| <div style="border: 1px solid black; padding: 5px; display: inline-block;"><b>MD</b></div>   | <p>Indicates that the device is a medical device</p>   |
| <div style="border: 1px solid black; padding: 2px; display: inline-block;"><b>REF</b></div>  | <p>Indicates the manufacturer's catalogue number so that the medical device can be identified.</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>An indication that electronic instructions for use are available<br/>Instructions can be obtained on the <a href="http://www.phonakpro.com">www.phonakpro.com</a> website</p>   |
|   | <p>Provides further clarification about a feature or functionality.</p>  |
|   | <p>Highlights relevant fitting information being applied</p>   |
|   | <p>Indicates a restriction in functionality that may impact the patient's experience or highlights important information that requires your attention</p>  |
|   | <p>HIMSA certification seal NOAHSEAL</p>   |

## Important safety information

Target 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 HCPs use Target in accordance with this User Guide and that they understand and heed the warnings contained herein.

In the case of Target, these risks manifest themselves through the hearing aids it is intended to program. That is, Target 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.



### High MPO

The output of both hearing aids exceeds 132 dB (ear simulator)



### High noise generator level

Noise generator level of both hearing aids exceeds 80 dB(A). Be aware of the maximum wearing time displayed in "Tinnitus balance" screen.



### Receiver problem

The selected and the detected receiver are not identical. Select the correct receiver.



### Wrong side information

The hearing aid is configured for the opposite side. Allow change of side.



### Connection warning

Based on age, a tamperproof solution should be attached to the hearing aid.



### Measurement settings

Remove the hearing aids from the patient's ears. Turn the hearing aid off and on again. All fitting data in the hearing aids can be restored at the end of the process.

## System requirements

|                                   |   |
|-----------------------------------|---|
| Operating system                  | <ul style="list-style-type: none"> <li>Windows 11, Home/Pro/Enterprise</li> <li>Windows 10, Home / Pro / Enterprise</li> <li>Windows 8.1, Pro / Enterprise</li> </ul>       |
| Processor                         | Intel Core or higher performance  |
| RAM                               | 4 GB or more  |
| Hard disk space                   | 3 GB or more  |
| Screen resolution                 | 1280 x 1024 pixels or more  |
| Graphic card                      | 16 Million (24bit) screen colors or more  |
| Drive                             | DVD   |
| Serial COM port                   | Only if RS-232 HI-PRO is used   |
| USB ports<br>One for each purpose | <ul style="list-style-type: none"> <li>Bluetooth adaptor</li> <li>Accessory programming</li> <li>HI-PRO if used via USB port</li> <li>Noahlink Wireless</li> </ul>          |
| Programming interfaces            | Noahlink Wireless/ iCube II/ NOAHlink/ RS-232 HI-PRO/ HI-PRO USB/ HI-PRO 2  |
| Noahlink driver                   | Latest version available  |
| Noahlink Wireless driver          | Latest version available  |
| Internet connection               | Recommended   |
| Sound card                        | Stereo or surround 5.1  |
| Playback system                   | 20 Hz – 14 kHz (+/- 5 dB), 90 dB  |
| NOAH version                      | Latest version (NOAH 4.4 or higher)<br>Please check the NOAH limitations for Windows 64 bit operating systems on<br><a href="http://www.himsa.com">http://www.himsa.com</a> |
| TargetMatch                       | Noah Version 4.4.2280 or higher<br>Natus® Otosuite 4.81.00 or higher<br>Natus Aurical FreeFit for REM & Aurical HIT for test box measurements                               |

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 Phonak Target 8.1



CE mark applied 2022

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