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User Guide

Phonak Target 12

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 phonak.com on the Phonak Target Support page. In addition, you can find [News] in Phonak Target within the notification sidebar.

Intended user
The fitting software is intended for qualified hearing care professionals.

Intended patient population
The intended patient population for the fitting software is the intended patient population of the compatible hearing aids.

Use environment
The intended environmental operating conditions of the device are given by the platform running the fitting software. The system requirements of the platform running the fitting software are found at the end of this user guide.

Indications
The fitting software has no therapeutic or diagnostic effect on its own. The therapeutic effect is given by the compatible hearing aid. For the indication of the compatible hearing aid, please refer to the corresponding User Guide(s).

Contraindications
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:

- 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
E	All released form factors
Infinio	All released 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

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 fitting software provides an indirect clinical benefit by enabling the hearing care professional to set the hearing aid to a patient's individual needs and to store the settings on the hearing aid.

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Structure and navigation

Refer to the Phonak Target Installer guide for installation guidance.
The three tabs [Client], [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 information and DataLogging consent, audiogram, RECD, and REUG are found within [Client].	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™ (NLW/NLW2)
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 programing 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.

A guide on how to clean and disinfect all devices that are used with multiple clients (e.g. trial devices, loaners) can be found via the [Help] function.

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 provide a starting point for flexible 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 tamper-proof solution will appear for children between 0-36 months when hearing aids are initially connected. If the available hearing aid does not have a tamper-proof 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.

Fitting Authorization

For hearing aids on the latest E platform, a fitting authorization security feature has been introduced. This feature prevents unauthorized changes to the fitting, and access to information stored on the hearing aids.

Fitting Authorization can be performed automatically, or manually if automatic methods are not possible.

Fitting Authorization is achieved in one of three ways:

Automatic:
- Noahlink Wireless 2 (NLW2) is connected to the PC
- You are logged into your HCP account* in Target via the person icon near the top right-hand corner
  *If available (e.g-PhonakPro account). Please contact your local manufacturer representative for more information.

Manual:
- Press and hold the button on each hearing aid for 8 seconds

After a successful first authorization with the hearing aid, a security association is stored in Target/Noah patient database. This automatically authorizes all future fitting sessions with the same patient record and hearing aid for in-clinic and Remote Support sessions.

For changes made outside a fitting session (e.g. reset to factory settings or changing the performance level of Trial devices) fitting authorization will be required again.

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.

Target has a ML (Machine Learning) system integrated into the software. The ML, AI Dome Proposer, is an advanced tool designed to assist HCPs in deriving optimal Acoustic Vent Mass (AVM) values for hearing aid domes, enhancing the fitting process and improving patient outcomes.

Accessories

Accessories can be manually selected in [Instruments] > [Accessories]. Click [Compatible] 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 measurements] / [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 ≥ 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.

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.
- 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.

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. 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.

Video conferencing platforms

Video conferencing platforms can be used with Remote Support. To activate this setup click [Setup] > [Remote Support & Internet] > [Remote Support] and check the tick box. Return back to the [Client & sessions] screen and click [without Audio/Video].

Once your patient enters the Remote Support section and starts a session they will see a 2 digit authorization code. You will need to enter this 2 digit code in Target to have access to the patient's fitting session.

This feature is only available if the patient has the latest version of myPhonak app.

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 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.phonak.com/en-int/professionals/innovations/target/user-guides

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.

For important product security information please consult the Phonak Target Cybersecurity Guide provided with the installation package.

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

CE 0459	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.
Name, address, date	Combined symbol "medical device manufacturer" and "date of manufacture" as defined in in EU Regulation (EU) 2017/745.
EU REP	Indicates the Authorized representative in the European Union. The EU REP is also the importer to the European Union.
MD	Indicates that the device is a medical device.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.

	This symbol indicates that it is important for the user to read and take into account the relevant information in these user guides.
	An indication that electronic instructions for use are available. Instructions can be obtained on the www.phonakpro.com website.
	Indicates a restriction in functionality that may impact the patient's experience or highlights important information that requires your attention.
	HIMSA certification seal NOAHSEAL

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.

Training on the fitting software is not required separately as it is typically included in the hearing care professional's formal education and qualification.

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.

The fitting software informs about restrictions in the following cases:

MPO
MPO exceeds 132dB SPL

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 100dB SPL while using AudiogramDirect.

Data Transmission
Fitting data are transferred to the hearing instrument.

Intended patient population
Device is fitted to patient population ≤36months

System requirements

Operating system	• Windows 11, Home/Pro/Enterprise/ Education • Windows 10, Home/Pro/Enterprise/ Education
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/ USB
Serial COM port	Only if RS-232 HI-PRO is used
USB ports One for each purpose	• Bluetooth adaptor • Accessory programming • HI-PRO if used via USB port • Noahlink Wireless (NLW/NLW2)
Programming interfaces	Noahlink Wireless (NLW/NLW2)/ 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	NOAH 4 latest version Please check the NOAH limitations for Windows 64 bit operating systems on http://www.himsa.com
TargetMatch	• NOAH 4 latest version • Auditdata Primus • Auditdata Measure • Interacoustics Affinity Suite • Interacoustics Callisto Suite • MedRx Studio • Natus® Otosuite • Signia Unity 3 • Signia Unity 4 • Otometrics Measure

More detailed information about supported versions available at:
https://www.phonak.com/en-int/professionals/innovations/target

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This user guide is applicable for Target 12.0 and later subversions of Target 12 fitting software. For previous versions of the fitting software user guide please contact your local Phonak representative.

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HEAR THE WORLD

CE 0459