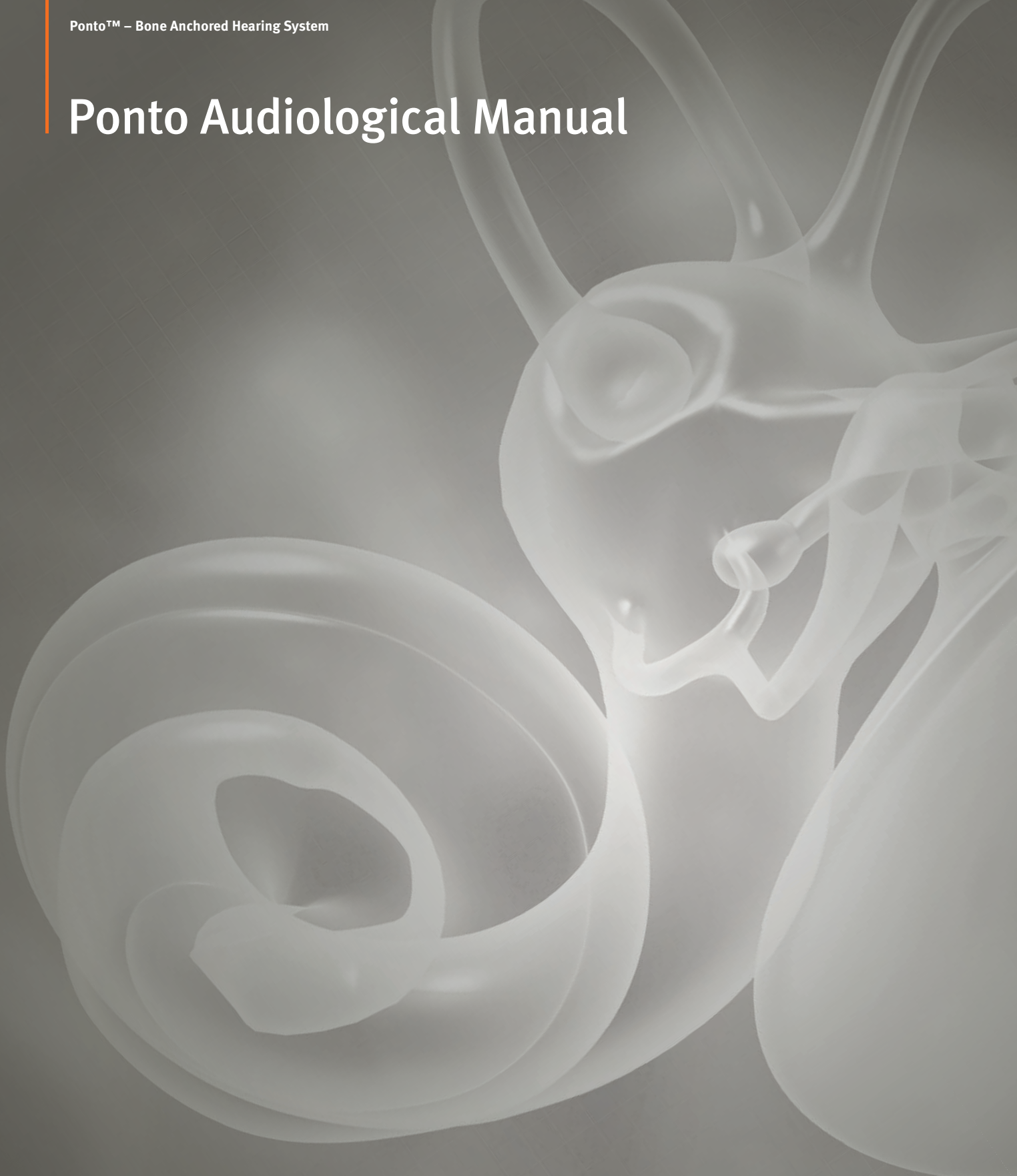


Ponto Audiological Manual



Choose Sound.
Choose Ponto



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MEDICAL

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Introducing the Ponto Bone Anchored Hearing System

The Ponto System is designed to give patients improved hearing through direct bone conduction. This manual provides detailed information for audiologists working with patients who have received a bone anchored implant and will be fitted with a Ponto sound processor.

Young children and other patients who are not suitable for implantation can still use a Ponto sound processor for longer periods of time on a head band or Softband. Please refer to the Ponto Candidacy Guide for information relevant to fitting on a Softband.

The Ponto System is a beneficial solution for several patient groups, including those with conductive or mixed hearing loss or single-sided deafness (SSD). If candidacy has yet to be determined, please refer to the Ponto Candidacy Guide for further information and instruction.

When surgery is elected, an implant is inserted into the skull bone behind the ear in a simple procedure. After a short period of time, during which the bone attaches to the implant through osseointegration, the sound processor can be connected to the abutment. Please refer to the Ponto Surgical Manual for further details on the implant process.

A range of Ponto sound processors are available. The sound processors are programmed with the Genie Medical fitting software which enables the audiologist to measure the patient's hearing threshold via the sound processor to achieve an initial setting of the device. Also, the audiologist can adjust the frequency response and adjust various signal processing parameters of the sound processor in accordance with a patient's individual hearing requirements. Programming and adjustments can be done in the office or, for some models, remotely. A guide to that fitting process is included in this manual.

Illustrations and images in this manual are not to scale and are not intended to display actual markings.



Fitting

Following healing time, the clinician will be responsible for fitting the sound processor, and educating the patient on the care and use of the Ponto System. The fitting procedure includes several aspects related to the physical fit and programming of the device.

Checking the abutment site

The abutment and surrounding skin area should be checked to ensure the surgical site is healed, healthy, and ready for processor loading.

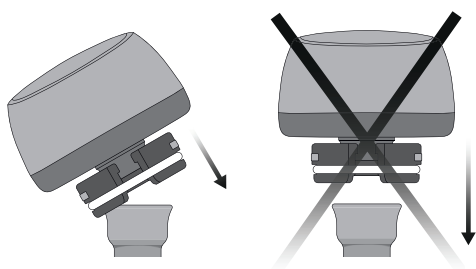


- Try to gently rotate the abutment to check that it is stable. If the connection is not stable, the connection should be tightened/adjusted by a health care professional (e.g. ENT surgeon or Audiologist).
- Inspect the skin surrounding the abutment, and remove any debris around or on the inside of the abutment.
- Inform the patient that in the event of persistent soreness and/or pain, he or she must contact the clinic. It is easier to treat skin irritations or infections at an early stage.

Practise operating the sound processor

- Explain the importance of keeping the coupling clear of hair and debris.
- Practise connecting and disconnecting the sound processor from the abutment.
- Practise operating the sound processor controls.
- Demonstrate sound processor features, such as volume control, push button, battery insertion and how to properly store the sound processor when not in use.

Detailed information on how to operate sound processor controls is included in the Instructions for Use.



Re-evaluate need for accessories

As described in the Ponto Candidacy Guide, again provide the patient with information regarding sound processor accessories, as their needs may change over time. Information on all sound processor features and functionalities can be found in the Product Information sheet and the Instructions for Use as applicable to each sound processor model.

Hygiene and maintenance

The patient should understand their responsibilities in the daily care of their implant and abutment site, care of the sound processor itself, and what to do if they have issues or questions.

Cleaning routines

It is vital to inform the patient about the importance of maintaining good hygiene in the area around the abutment of the bone anchored implant. Caring for the implant site is a simple process that will become part of the patient's daily routine.



A mirror may be helpful when cleaning the implant site.

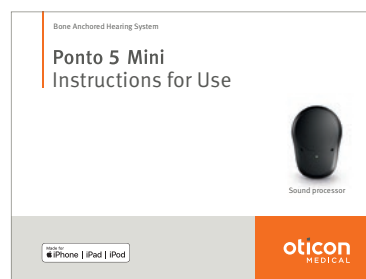
- The skin should be thoroughly cleaned of debris every few days. While washing the hair with mild shampoo, debris becomes softer and is more easily removed.
- Instruct the patient to maintain a simple daily cleaning routine using soap and warm water.
- Use a moist cotton swab to clean around the outside and towards the inside of the abutment. If the patient is bilaterally implanted, separate cotton swabs should be used for each abutment.
- Note the importance of cleaning both inside and all around the skin-penetrating abutment. This is important to prevent debris build-up.

Service and repair

It is important that the patient handles the sound processor with care and maintains proper hygiene to avoid unnecessary service and repair. Recommendations for handling and precautions are given in the sound processor Instructions for Use.

Go through Instructions for Use

Go through the sound processor Instructions for Use together with the patient to make sure the content is understood. Pay extra attention to Important Patient Information and Warnings, and to the information on maintenance of the sound processors.



Note: Example illustration only. Instructions for Use are available for each sound processor model.

Programming guidelines

Genie Medical fitting software is NOAH compatible and can also run in stand-alone mode with its own database.

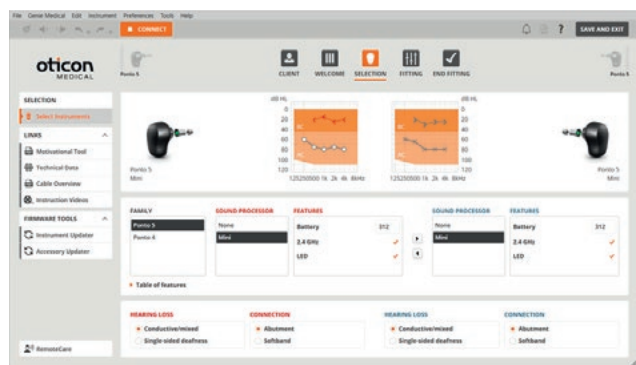
Programming device

The Ponto 4 and Ponto 5 sound processors can be programmed wirelessly using the Noahlink Wireless. All sound processors can also be connected to the PC using a standard programming device such as Hi-Pro 2 or ExpressLink.

Below is a guide to the recommended programming flow.

Selection step

- Select instrument
- **Select type of hearing loss**
 - Conductive / mixed – if the sound processor is fitted to a patient with conductive or mixed hearing loss (default selected).
 - SSD – If the sound processor is fitted to stimulate the cochlear on the opposite side.
- **Select type of connection**
 - Abutment – if the patient is using the sound processor on an implant and abutment (default selected).
 - Softband – if the sound processor is fitted on a Softband or head band.



Fitting step

- Connect the sound processor to the patient's abutment. Mute the sound processor if necessary to avoid feedback.
- Measure the individual feedback limit in the **Feedback Analyser** tool. If programming cable is used, please ensure that the cable does not pull the device and evoke feedback.
- Conduct **BC In-situ Audiometry**.
- Evaluate the settings and, if necessary, adjust the settings.

End Fitting step

- Click Save and Exit.

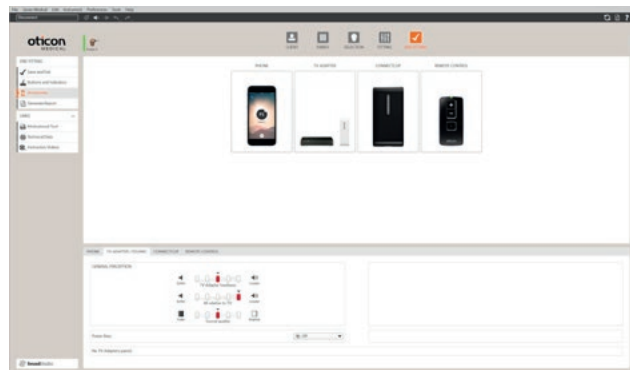
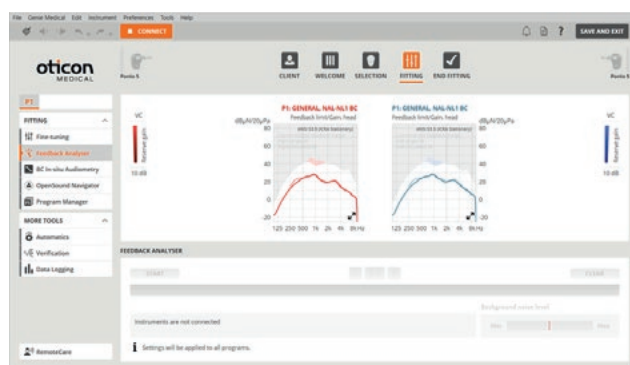
For technical verification of the processor, refer to page 9.

Streaming to the sound processor – no need for programming in Genie Medical

- Ponto 4 and Ponto 5 sound processors: No specific programming is needed in Genie Medical to get the sound processor to receive signal from e.g. ConnectClip or TV Adapter. The sound processor and the wireless connectivity devices just need to be paired following the instructions included with the wireless accessory.

The sound from the wireless connectivity devices can be fine-tuned in the tool Accessories in the End Fitting step.

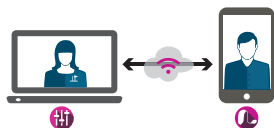
More detailed information can be found in the Genie Medical BAHs help files.



RemoteCare

RemoteCare lets you conduct a follow-up fitting session with a patient located elsewhere.

The fitting takes place in Genie Medical BAHS and the patient wearing the sound processors is connected via the app for RemoteCare.



RemoteCare is available in Ponto 5 or newer sound processors.

Before using RemoteCare

Before you can conduct your first RemoteCare session, you must contact Oticon Medical to be set up as a user, and you must ensure that you and the patient meet the technical requirements for using RemoteCare.

Getting ready for a RemoteCare session

Make sure that the patient does the following before the remote session begins:

- Plugs the device (e.g. smartphone) into a power supply or ensure that the device is fully charged, and that Bluetooth is turned on.
- Ensures that the sound processor(s) have new batteries.
- Pairs the sound processor(s) with the device. For Apple® devices, the patient must pair the sound processor(s) with the device before the app for RemoteCare can be used.

For Android™ devices, the patient can pair the sound processor(s) in the app for RemoteCare.

- Is online and logged in with the email account used to create the RemoteCare account.

How to log in to RemoteCare

1. Select your client in the Client step if you are using the Genie Medical BAHS stand-alone or from the patient browser in NOAH.
2. Click RemoteCare in the task pane. A window opens outside Genie Medical BAHS where you can enter your login information. The RemoteCare window will then open.
3. Select the desired camera and microphone source from the drop-down lists.
4. Enter your patient's email to establish the remote session. The window displays the client's status.
5. If your patient has already logged in and is waiting in the virtual waiting room, you can start the remote fitting session.







In case of connection problems, see Troubleshooting RemoteCare in the Genie Medical BAHS help files.

How to conduct a session in RemoteCare

1. Click Start a visit. Connect the sound processor(s) by clicking Connect in the toolbar.
2. In Genie Medical BAHS, you can now modify the fitting as you would in an in-office fitting session.
3. Ensure that Genie Medical BAHS is connected to the sound processor(s) and click Upload to apply the new setting. Be sure to upload after each change to the sound processor(s), so your patient can evaluate the change. In the communication window, there are icons and status indicators that let you communicate with your patient and view the status of the sound processor(s).

How to end a session in RemoteCare

1. Tell your client that you will be ending the session. Ensure that you have saved all changes.
2. When you are finished, click Disconnect to disconnect the sound processors from RemoteCare. The sound processor(s) will restart.
3. In the End Fitting step, click Save and Exit (NOAH) or Save and go to Client step (stand-alone) to save and end the session.

	Refresh video.
	Turn the camera on or off.
	Turn the microphone on or off.
	Show or hide the chat panel.
	If the icon appears next to the chat icon, you have unread chat messages.
	Upload settings to the sound processors. The upload icon becomes active when you have new settings to upload. When there are no new settings to upload, the icon is greyed out.



Follow-up evaluation

To get the maximum benefit from Ponto, it is recommended that the patient attends follow-up sessions after the initial sound processor fitting. The frequency of these appointments will depend upon the clinic's specific protocol. Information regarding both short-term and long-term care is offered in this section.

Follow-up suggestions

It is recommended that the first follow-up visit takes place within two months of the initial fitting. Subsequent appointments once or twice a year will be sufficient to ensure proper maintenance, but some patients may require more frequent appointments.

Medical device regulations require the manufacturer to report serious incidents to the appropriate authority. Should an incident occur, notify your local distributor or the manufacturer as soon as possible.

Subjective measurements

It is recommended to let the patient and/or the patient's family complete a questionnaire that aims to evaluate how much they benefit from and their satisfaction with the sound processor over time.



SKS 10 Skull Simulator



Audioscan Verifit
Skull Simulator

Objective measurements

Aided word recognition testing in quiet and in noise

It is recommended to measure the patient's word recognition score in quiet and in noise. Speech testing, particularly in the presence of background noise, can provide helpful information to the clinician and the patient about the patient's progress.

Aided sound field threshold measurements

Aided threshold measurement may be conducted, but be aware that this test is affected by a number of variables, such as loudspeaker set-up, test signal, the setting of the sound processor, and the patient's position in the test environment. If warble tones are used as the test signal, the sound processor's feedback cancellation/feedback management needs to be turned off prior to testing.

Technical verification of the sound processor

A Skull Simulator can be used to technically verify the sound processor performance, serving several clinical purposes.

- Checking the performance of sound processors used during a preoperative trial period.
- Measuring the sound processor in user settings for comparison at follow-up meetings.
- Testing the sound processor in technical settings, and comparing it to its product information, to assess a patient complaint of a faulty device.





Paediatrics

Evaluating and fitting children with a bone anchored sound processor involves some special considerations. Parents of hearing impaired children generally have greater need for counselling. The treatment should be discussed with a parent or caregiver from a short as well as a long term perspective.

The Softband is a valuable tool for evaluation as well as for fitting before the implantation can be performed. It is typical for children to use the Softband for a longer period of time prior to implantation.

Considering implantation

It is recommended that children are fitted with the sound processor on a Softband before they can be considered as a candidate for implantation. With the Softband the child can be fitted early to gain access to improved language, speech and educational development.

Before a bone anchored implant can be successfully implanted the bone must be thick enough and sufficiently hard. For detailed information on required bone thickness and special consideration for paediatric patients, see the Ponto Surgical Manual.

Note: In the US, Canada, and Singapore, the placement of a bone anchored implant is contraindicated in children below the age of five.

Care

In many cases, the child patient will not be personally responsible for the care of their processor, Softband, or once they have undergone surgery, the implant site. It is important that the parent or caregiver of the child is aware of their responsibilities, and the impact of their care on the outcome of their child's hearing health.



Fitting

There are several special considerations, and subsequent selections to be made in the Genie Medical fitting software when working with paediatric cases. Refer to the adult programming guidelines on page 6 of this manual, and consider the following:

Obtaining BC thresholds

Some patients may be too young to provide reliable behavioural testing results. We recommend using the BC In-situ tool as soon as possible; however, estimated BC thresholds can be entered into Genie Medical until the child is old enough to participate. This information may come from Auditory Brainstem Response (ABR) testing, Auditory Steady State Response (ASSR) testing, Behavioural Response Audiometry (BOA), or Visual Reinforcement Audiometry (VRA). If no BC values are entered then Genie Medical prescribes gain for a BC hearing threshold of 0 dB HL.

Placement of the sound processor

Some children will wear their Ponto sound processor in varying locations on the skull. For very young children, it is possible to place the processor on the child's forehead for best access to environmental and speech sounds. If the processor is to be worn in this location, we recommend that the directionality setting be changed to Omni to ensure maximum benefit. For children wearing the processor on one side specifically, the default microphone setting of Open Automatic is recommended.

Childproofing options

When fitting children below the age of 36 months, it is important to secure that the device is fitted with a tamper resistant battery drawer, which will prevent young children from removing the battery on their own.

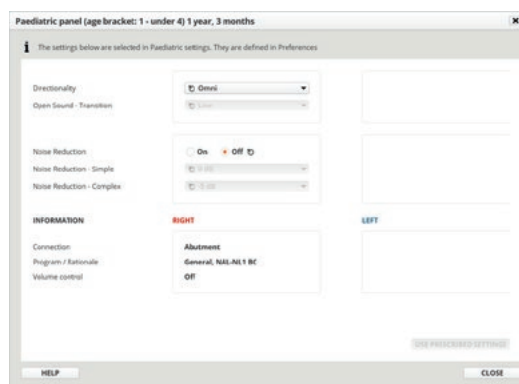
Ponto sound processors either have a built-in tamper resistant battery drawer or an exchangeable battery drawer included in the instrument box. Follow the Instructions for Use and product specific instructions on how to attach and use the tamper resistant battery drawers.

Please check that children and others in need for a tamper resistant option have the correct battery drawer fitted before leaving the clinic.

Other practical considerations of fitting children include deactivating default controls, such as the mute functionality and the volume control. In the End Fitting step, select the Buttons and Beeps task, and uncheck the boxes to disable these functions.

Physical considerations

A safety line is included with the processor, which will connect it to a clip that can be attached to the child's clothing. Even if the child removes the processor from the Softband or abutment, it will remain attached to their clothing to prevent loss of the device.



Follow-up evaluation

Depending on the age of the child, and whether they have an implant or are using the processor on a Softband, the number and frequency follow-up appointments will vary.

Subjective measurements will more often involve input from the child's family.

- Ask the child's parent or caregiver about practicalities of use and provide additional counselling or instruction if needed.
- Use survey tools to track the child's progress over time.

Objective measurements may need to be tailored to the child's age and fitting status.

- It may not be possible to complete aided word recognition tasks, depending on the child's language development level.
- Aided sound field measurements for verification may not be obtainable until the child is older.
- The sound processor can be technically verified using a skull simulator in the same way as described in the adult fitting section, page 9.

Accessory use

Like conventional hearing instruments, the Ponto System has the ability to work with FM systems, EduMic and Connectivity devices. These options should be considered for paediatric fittings, especially for school-aged children who could benefit from additional assistance in the classroom.

Cosmetically, the Ponto sound processors feature a colour palette which is designed to blend with many hair colours. For patients who wish to personalise their processor, both stickers and skins are available. The Softband is also available in several colours. Detailed information on all products is available in the Ponto Product Catalogue.



Compatibility Guide


Products that can be used with the Ponto System

Ponto System components	Products with ref. no. manufactured by Cochlear Bone Anchored Solutions AB
Ponto Sound Processor Family Ponto 5 Ponto 4	Compatible products from Cochlear BAS Baha® abutments (90305, 90410) Baha® implants with abutment (90434, 90480)
	Incompatible products from Cochlear BAS Baha® BA300 Series abutments Baha® BA210 Series abutments Baha® BA400 Series abutments
Ponto Implant System Ponto Implants with pre-mounted abutments Ponto Abutments	Compatible sound processors from Cochlear BAS Baha® 5 SuperPower (96004, 96003, 96002, 96001) Baha® 6 Max (P1668389, P1668390, P1668391, P1668392, P1668393, P1668394)
Ponto Sound Processors	Genie Medical Fitting Software
Ponto Sound Processor Family Ponto 5 SuperPower Ponto 5 Mini Ponto 4	Genie Medical Fitting Software Genie Medical BAHS 2022.1 and later Genie Medical BAHS 2021.1 and later Genie Medical BAHS 2019.1 and later

Oticon Medical Ponto series sound processors and abutments used together with the above listed sound processors and abutments from Cochlear Bone Anchored Solutions AB secure similar sound transmission, connection force and disconnection force. The sound quality and experience are determined by the sound processor that is being used.

Not all products are available in all markets. Product availability is subject to regulatory approval in the respective markets.



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