

Hearing Services Program: Minimum Specifications for Subsidised Devices

PREPARED BY THE NATIONAL ACOUSTIC LABORATORIES FOR THE
AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGED CARE

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1.1	08/09/2024	Pdraig Kitterick	Revised report following feedback from suppliers. Key changes were: <ul style="list-style-type: none"> • Removal of transient noise reduction feature requirement from hearing aid categories • Clarification that client choice requirements should be interpreted as applying at the hearing aid device category level, and not at the supplementary category level • Clarification that the client choice requirement related to telecoil does not apply to devices listed in the HA NC category • Revised wording for technical requirement for the lifespan of rechargeable hearing aid batteries • Removal of technical requirements relating to device lifespan

Table of Contents

Executive summary	5
Section 1: Background.....	6
Overview	6
Section 2: Methods for developing recommendations.....	8
Overview	8
Scoping review	9
Feature summary	9
Categorisation.....	9
Consolidation	10
Section 3: Recommendations for device categories	11
Section 4: Recommendations for hearing aids.....	16
Scoping review	16
Summary of prevalence of features.....	17
Considerations for developing minimum specifications for hearing aids	19
Key considerations	19
Recommendations for feature requirements	22
Recommendations for client choice and access requirements.....	25
Recommendations for technical requirements.....	26
Section 5: Recommendations for assistive listening devices.....	28
Scoping Review.....	28
Summary of prevalence of features.....	29
Considerations for developing minimum specifications for ALDs	33
Key considerations	33
Supported Self-Fitting (ALD SSF) Hearing Devices.....	33
Recommended for feature requirements	35
Recommendations for technical requirements.....	35
Section 6: Minimum Specifications for Cochlear Implant Sound Processors	36
Scoping review	36
Summary of prevalence of features.....	36
Recommendations for feature requirements	39
Recommendations for technical requirements.....	39
Section 7: Minimum Specifications for Bone Conduction and Middle Ear Devices	41
Scoping review	41
Summary of prevalence of features.....	41

Feature requirements.....	43
Recommendations for technical requirements.....	44
Section 8: Discussion	46
Section 9: References	48
Appendix 1: Recommendations for the Minimum Specifications for Subsidised Devices	50
Section A1: Hearing device categories	50
Section A2: Minimum Specifications for Hearing Aids	53
Section A3: Minimum Specifications for Assistive Listening Devices	57
Section A4: Minimum Specifications for Cochlear Implant Sound Processors	58
Section A5: Minimum Specifications for bone conduction Bone Conduction Sound Processors.....	60
Section A6: Definitions of device features	62

Executive summary

This document describes recommendations for the minimum specifications that the Hearing Services Program of the Department of Health and Aged Care should require all subsidised devices (whether fully- or partially-subsidised) to meet in order to be listed on any of the Program's schedules of devices.

The recommendations have been developed using the principles that they should:

- (1) Reflect the features that are widely available in subsidised devices being provided on the Program at the present time;
- (2) Ensure there is increased access to newer technologies for clients of the Program;
- (3) Allow manufacturers to introduce new technologies or innovations that benefit the client without deterrents; and
- (4) Ensure there is continued access to core assistive technologies that remain important for certain subsets of Program clients.

Key highlights from the recommendations contained in this document are as follows:

- Significant expansion in the number of features that all subsidised devices (whether fully- or partially-subsidised) are required to have to reflect what features are already available in the overwhelming majority of subsidised devices at the time this report was produced;
- Redefinition of the categories of devices to introduce:
 - new categories for families of devices not previously listed on the Program and that may be considered for inclusion in the Program in the future (e.g. cochlear implant sound processors);
 - standard categories for devices previously listed on the Program but as non-standard devices (e.g. assistive listening devices, bone conduction devices);
- Introducing specific requirements for listing devices on the Program's device schedules to both ensure clients can access the latest in technology while also ensuring key legacy assistive technologies such as telecoil and manual controls remain available to those clients of the Program who need them;
- Reformulating the minimum specifications so that they not only specify the essential requirements a device needs to meet in order to deliver sufficient quality for the Program and for Program clients but do so in a way that does not impede manufacturers in adopting newer technologies and introducing innovations in how they meet those requirements.

The full set of recommendations are listed in Appendix 1 of this document.

Section 1: Background

Overview

The scope of the Independent Review of the Hearing Services Program ('the Program'), commissioned by the Australian Government in 2020, included examining whether the Program delivers services aligned with clinical need and contemporary service delivery.

In its report, the Hearing Services Program Review Expert Panel made specific recommendations related to broadening the scope of technology provided under the Program both to keep pace with technological advancements and to facilitate greater client choice. Those recommendations included the following:

- 18(a) *The Australian Government should evaluate the benefits and costs of including developing technologies, such as rechargeable devices and batteries, directional microphones, alerting devices, mobile applications, and remote controls, in the Schedule of Service Items and Fees.*
- 18(b) *The Australian Government should commission the following reviews and convene one or more broad sector working groups of stakeholders, including consumer representatives, to participate in them:*
 - a review of hearing technologies which should be listed under the Hearing Services Program
 - a review of the minimum specifications for fully subsidised hearing devices under the Hearing Services Program as outlined in manufacturers' Deeds of Standing Offer and the criteria which guide the inclusion of those devices in the Deeds of Standing Offer.

In 2022, the Department of Health and Aged Care ('the Department') commissioned the National Acoustics Laboratories (NAL) to conduct a review of contemporary hearing technologies, including both the features commonly available in hearing devices and novel emerging technologies. As a result of this work, the Guide to Hearing Technology was delivered in 2023 and is now available on the Program's website. The Department subsequently commissioned NAL to undertake work to inform ongoing work to assess program technologies, improve the consistency of device and service terminology, and update minimum standards or specifications of common technology features.

Problem Statement

Only approved devices can be supplied to clients under the Program. Approved devices include devices that are listed on the Fully or Partially Subsidised Schedules of Approved Devices or are otherwise approved by the Department under non-standard approval processes. To be listed on the device schedules, device suppliers must certify they meet minimum specifications, as currently set out in the Deed of Standing Offer. The Independent Review of the Hearing Services Program recommended that Program review the hearing technologies that might be provided to clients and subsequently updating the minimum specifications for subsidised devices. To update the minimum specifications requires a review of current features available in devices provided under the Program and consideration of both how legacy and emerging technologies should be incorporated, as required, to meet the needs of the Program's clients.

Intended benefits

The intent of the work described in this report is to enable the Department to update the minimum specifications for devices subsidised under the Program and to support it in fulfilling the recommendation of the Independent Review of the Hearing Services Program that program service delivery be improved by reviewing and updating the minimum specifications of subsidised devices.

Aim and objectives

The overall aim of the current work undertaken by NAL was to inform the Department's ongoing work to assess current and potential future Program technology.

The specific objectives of the current work were to:

- (1) Deliver a minimum specification for subsidised hearing devices under the Program to cover:
 1. Hearing Aids;
 2. Assistive Listening Devices;
 3. Specialised devices that may be considered for inclusion in the Program in the future (e.g. cochlear implants processors);
 4. Any other recommended technologies NAL identifies for inclusion based on the needs of the Program's clients.
- (2) Define categories of devices for the Department to use for determining reimbursement and reporting requirements.

Section 2: Methods for developing recommendations

Overview

The project had multiple activities which ran in parallel, where possible. The project work comprised four key activities (Figure 1). The four key activities are expanded on below.

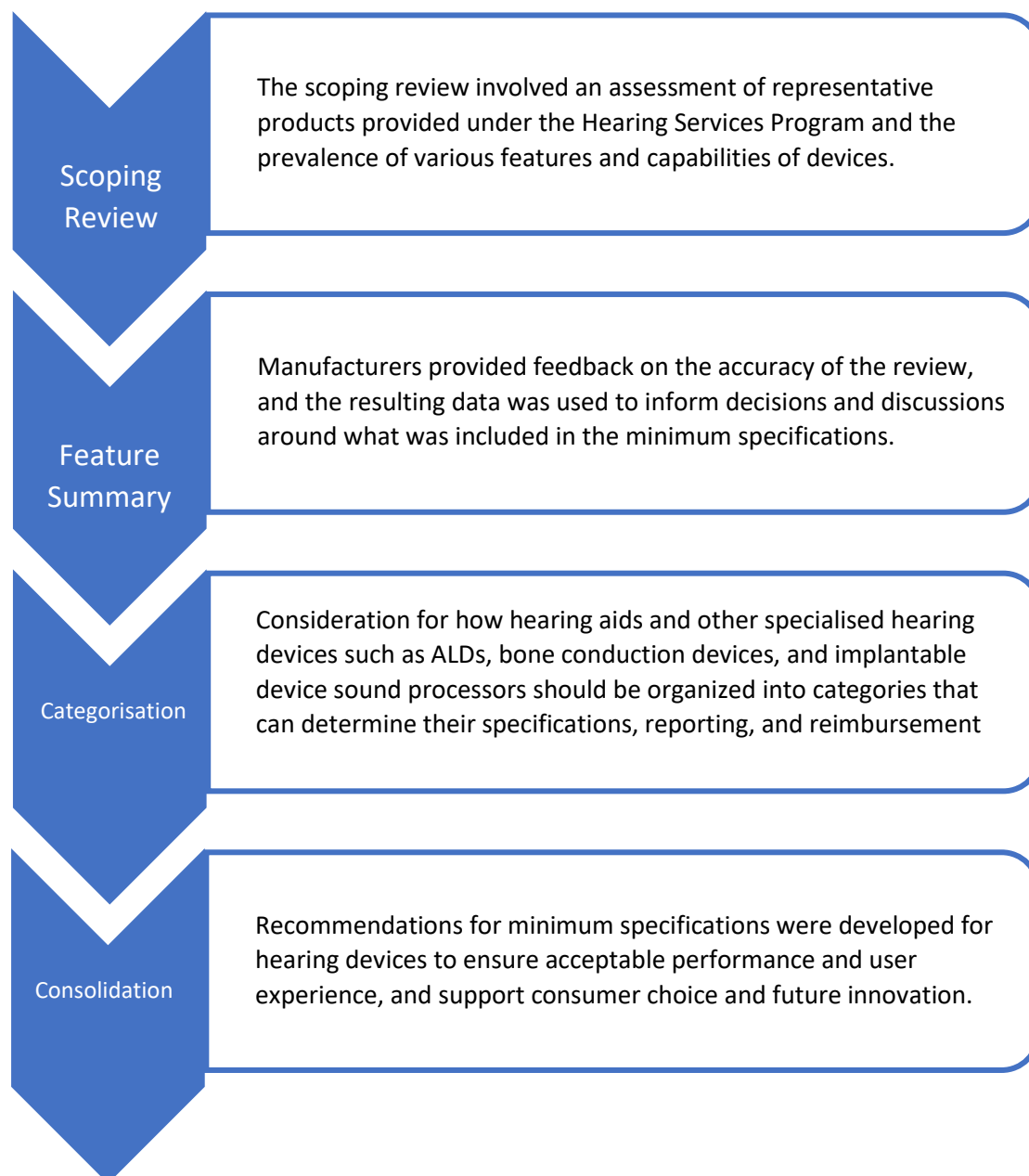


Figure 1: Schematic overview of the method for developing recommendations.

Scoping review

A subset of device models provided as fully-subsidised devices under the Program were selected for inclusion in the current review. These devices comprised Hearing aids (HAs), Assistive listening devices (ALDs), and any specialised devices that are routinely provided under the non-standard processes of approval under the Program (e.g. bone conduction and contralateral routing of signals devices). The selection of devices for inclusion in the current review was informed by data on all fittings and replacements (not including spare aids) of fully subsidised devices under the Program between 1 July 2022 and 30 June 2023. Specifically, the models of each type of device chosen for review (e.g. behind-the-ear HAs) represented at least 90% of the volume of devices of that kind that had been supplied under the Program during that period. As such, the results of the review could be assumed to represent the features that are available in the overwhelming majority of devices available to clients of the Program.

Where only a small number of device models had been provided by the Program (e.g. bone conduction devices), best efforts were made to include all devices provided during the period for which supply data was available in the review. For the review of cochlear implant sound processor devices, no existing data was available from the Program on device provision. Therefore, representative models of cochlear implant sound processors were selected from devices currently approved by the Therapeutic Goods Administration (TGA).

Feature summary

For each device selected for review, publicly available product literature and device specifications were obtained from manufacturer websites. Where such information could not be obtained, best efforts were made to obtain equivalent information from device suppliers or direct from the manufacturer, if required. Features were categorised using the lexicon of hearing device features developed previously by NAL for the Department (see Section A6), and the availability of different features was tabulated across all devices included in the review.

The initial determination of which features were available in each device included in the review was shared with the manufacturer of that device. This process was intended to solicit feedback on the accuracy of the review in capturing which features are available in each device, acknowledging that the extent of publicly available information may limit the accuracy with which features can be identified and determined to be present in the wide array of device models and technology levels offered by each manufacturer. This process ensured that further consideration of which features to include in the minimum specification was based on accurate information on how widely available those features already are to clients of the Program.

Categorisation

An analysis of the landscape of features across different types of devices (e.g. HAs and ALDs) and different models or form-factors of the same type of device (e.g. behind-the-ear and receiver-in-the-canal hearing aids) was conducted to determine how devices should be organised into different categories. Five considerations were taken into account when determining the need for establishing a specific device category:

- (1) whether a certain subset of devices were likely to have unique requirements when it came to developing a minimum specification;

- (2) whether the Department may have a need to track the statistics around provision of a particular subset of devices (given that the Department has advised that categories are integral to the current processes for listing, providing and reporting of devices);
- (3) whether the Department may have a need to set a specific reimbursement level for a particular subset of devices (given that reimbursement levels are specified at the level of device categories in the current Deed of Standing Offer);
- (4) whether there are non-standard devices that are sufficiently coherent in their feature set and consistent in their provision under the Program that warrant a category to be established for those devices; and
- (5) whether it is necessary to establish a category for a subset of devices that may already be provided at low volumes and for which few models are currently on the market, but whose provision is considered likely to increase significantly in the foreseeable future (e.g. over-the-counter & self-fitting hearing aids).

Consolidation

Using the outputs of the feature review and after obtaining feedback from device manufacturers and organising devices into categories, the project team then proceeded to identify:

- The minimum set of features of devices in each category that are widely available to clients of the Program in fully-subsidised devices (i.e. 'lowest common denominator' feature set);
- Any features that are particularly desirable to consumers (based on inputs such as existing market research and NAL's knowledge of the sector) and may warrant inclusion in a minimum specification but may not yet be represented in this lower common denominator feature set;
- Performance requirements for specific features, where possible, to ensure that subsidised devices achieve an acceptable level of functionality;
- Essential technical requirements that describe functional requirements of devices beyond just the inclusion of specific features, but only where considered necessary.

Section 3: Recommendations for device categories

The following section presents the device categorisations that have been developed to support the new proposed minimum specifications and the Program's requirements around reimbursement and reporting.

The rationale for determining how hearing devices should be organized into categories was based on recommendations from the independent review of the Hearing Services Program (Woods & Burgess, 2020). These recommendations aim to keep pace with technological advancements, broaden the scope of available technology, and enhance client choice.

New technologies and/or specialist devices that are not currently categorized under the Program were identified for inclusion based on consumer demand or expected future availability. As a result, categories for specialist devices such as ALDs, bone conduction devices, and implantable device sound processors were developed and included in the recommendations.

It is intended that devices provided under the Program would be listed under a single device category, excluding those that may continue to be provided via the Program's non-standard approval processes. Table 1 defines the recommended categories together with a rationale for their inclusion. Table 2 provides additional supplemental categories that can be applied to devices listed in categories for Hearing Aids. A detailed description of each category suitable for assisting manufacturers with selecting the appropriate category for any specific device is provided in Table 3.

Table 1. Recommended device categories and rationale

Device Category	Device Type	Rationale for inclusion
Hearing Aids (HA)		
HA BTE	Behind the ear (BTE)	Category that consolidates multiple previous BTE-related categories that are no longer relevant to distinguish between.
HA RIC	Receiver in the canal (RIC)	New category in line with how manufacturers categorise their hearing aid models. It is noted that 'RIC' is not defined in the corresponding legislation (schedule of service items and fees) so may need to be added if such definitions continue to be included in the supporting legislation.
HA C	Custom ITE, ITC, CIC, or IIC	Custom-molded hearing aids. These terms are used to be consistent with the corresponding legislation (schedule of service items and fees). Any changes in terminology here may need to be reflected there if such definitions continue to be included in legislation.

Device Category	Device Type	Rationale for inclusion
HA NC	Non custom (NC) ITE, ITC, CIC, or IIC	New category established for these non-BTE and non-RIC devices that do not require a custom mold. These devices have various domes to fit a wide range of ear canals.
Assistive Listening Devices (ALD)	Device type	Rationale/Notes
ALD TM	TV/Music (TM) Hearing Systems	New category consistent with DVA RAP Schedule and to highlight a common type of ALD.
ALD PS	Personal Sound Amplifier (PS) (without TV/Music Hearing System feature)	New category consistent with DVA RAP Schedule and to highlight a common type of ALD.
ALD PS +TM	Personal Sound Amplifier (PS) (with TV/Music Hearing System feature)	PS +TM category established to highlight the relatively small number of personal listeners which include this additional capability for cases when clinically relevant.
ALD SSF	Supported Self-Fitting (SSF) Hearing Devices	New category established for Self-Fitting/Hearable solutions which are unique to other categories and have the potential to grow in proportion or demand in the foreseeable future.
Contralateral and Bi-Contralateral Routing of Signals (CROS/BiCROS)	Device type	Rationale/Notes
CROS	Contralateral and Bi-Contralateral Routing of Signals (CROS/BiCROS)	New single category established for CROS devices. Department advised that current use of separate CROS/BiCROS categories is often arbitrary and inconsistent. CROS or BiCROS are overwhelmingly the same device; the distinction being only in how the device is programmed to address client needs.
Cochlear Implant Sound Processors (CISP)	Device type	Rationale/Notes
CISP BTE	Behind the ear (BTE)	New category established for cochlear implant sound processors, given the rising prevalence of such medically implanted devices and the potential for future provision under the Program.

Device Category	Device Type	Rationale for inclusion
CISP OTE	Off the ear (OTE)	New category established for cochlear implant sound processors, given the rising prevalence of such medically implanted devices and the potential for future provision under the Program. Note that 'OTE' is used to refer to an "Open Ear Device or Over-The-Ear device" in the current minimum specification. The repurposing of this acronym is in line with common use in the industry today and is not anticipated to create any confusion among manufacturers.
CISP BTE + EAS	Behind the ear (BTE) (with Electro-Acoustic System)	New category established for cochlear implant sound processors, given the rising prevalence of such medically implanted devices and the potential for future provision under the Program. Sound processors that deliver both electrical and acoustic stimulation (EAS) through one integrated device are now available for cochlear implant recipients whose residual hearing is preserved postoperatively in the implanted ear.
Bone Conduction Sound Processors (BCSP)	Device type	Rationale/Notes
BCSP IMT	Integrated mechanical transducer (IMT) that can be worn on an abutment or headband	New category established for contemporary bone conduction sound processors that conduct sound via an integrated vibrating mechanical transducer, previously provided via the non-standard process.
BCSP NMT	Non-integrated mechanical transducer (NMT) that operates in conjunction with a surgical implant	New category established for contemporary bone conduction sound processors that does not generate vibrations directly, but rather communicates with or connects to an implantable component that generates the vibrations required to achieve the bone conduction of sound.

Devices listed in any device category for Hearing Aids (HA) may also be listed with one or more of the device supplements listed in Table 2.

Table 2. Device supplements

Device supplement	Supplement qualifications
Hearing Aids (HA)	
HA +R	Battery is rechargeable (R)*
HA +HP	High powered (HP) device with OSPL90 \geq 128SPL

*Note that this supplement only relates to the internal battery and does not imply that a means of charging the battery is to be provided free-of-charge with the device.

Definitions for each category to assist manufacturers in selecting the most appropriate category for their device is provided in Table 3.

Table 3: Definitions of device categories

Device category	Technical definition
Hearing Aids (HA)	
Behind the ear (HA BTE)	An ear-worn hearing aid in which the sound is produced using a transducer located internal to the hearing aid itself and coupled to the ear canal using a tube.
Receiver in the canal (HA RIC)	An ear-worn hearing aid in which the sound is produced using a transducer located inside the ear canal.
Custom ITE, ITC, CIC, or IIC (HA C)	A hearing aid worn in the ear (partly or fully in the canal) whose shape is personalised to the wearer using a custom molded shell.
Non custom (NC) ITE, ITC, CIC, or IIC (HA NC)	A hearing aid worn in the ear (partly or fully in the canal) which is coupled to the wearer's ear using various domes to fit a wide range of ear canals.
Assistive Listening Devices (ALD)	
TV/Music Hearing Systems	An Assistive Listening Device which is explicitly designed to connect to a television or other audio source and transmit the sound to the user via earphones, headphones, telecoil, or another headset.
Personal Sound Amplifier	An Assistive Listening Device which is designed to provide the user basic amplification of acoustic sound via earphones, headphones, telecoil, or another headset. These devices are generally hand held or body worn and consist of an amplifier component that is separate from the ear-worn component.
Personal Sound Amplifier with TV/Music Hearing System Feature	A Personal Sound Amplifier ALD which includes an additional component, in the form of an audio transmitter, which allows for the additional function of a TV/Music Hearing System.
Supported Self-Fitting (SFF) Hearing Devices	A self-contained ear-worn device or set of devices which provide personalised acoustic amplification to the wearer by means of a self-fitting or hearing assessment feature, pre-defined sound profile, or limited choice of preset profiles.
Contralateral and Bi-Contralateral Routing of Signals (CROS/BiCROS)	
Contralateral and Bi-Contralateral Routing of Signals (CROS)	A device which is intended as part of its core functionality to re-route signals detected on the side of a poorer-hearing ear and reproduce those signals in a better-hearing ear, including devices that also provide amplification to address hearing loss in the better-hearing ear.

Device category	Technical definition
Cochlear Implant Sound Processors (CISP)	
Behind the ear (CISP BTE)	An ear-worn device that communicates with or connects to the implantable component of a cochlear implant system. These devices attach magnetically to the receiver/stimulator package of the implantable component wherever it is located on the head.
Off the ear (CISP OTE)	A device that is designed to be worn off the ear that communicates with or connects to the implantable component of a cochlear implant system. This do not include BTE processors that can be adapted to be worn off the ear using accessories; such processors should be listed in the CISP BTE category.
Behind the ear (BTE) (with Electro-Acoustic System) (CISP BTE + EAS)	A behind-the-ear sound processors that is configured such that it is capable of delivering both electrical and acoustic stimulation (EAS) through one integrated device; that is, it can both fulfil the functionality of a cochlear implant sound processor and act as an acoustic hearing aid
Bone Conduction Sound Processors (BCSP)	
Integrated mechanical transducer (BCSP IMT)	A bone conduction device with an integrated mechanical transducer that converts electrical audio signals into mechanical vibrations, including devices that can be worn on an abutment or headband. These vibrations are then transmitted through the bones of the skull to the inner ear, bypassing the outer and middle ear.
Non-integrated mechanical transducer (BCSP NMT)	A sound processor that does not generate vibrations directly, but rather communicates with or connects to an implantable component that generates the vibrations required to achieve the bone conduction of sounds.

Section 4: Recommendations for hearing aids

The following section presents the information that underpins the recommendations for the minimum specifications for hearing aids. The recommendations were determined following a scoping review and analysis of identified feature technologies that were currently present in fully subsidized devices provided under the Program or new technologies that should be considered for inclusion on the basis of consumer demand or expected availability over time.

Scoping review

The scoping review determined the prevalence of various features in hearing aids currently subsidised under the Program. This review was based on subsidised device listing and supply data across a period of 12 months (2022-2023), as provided by the Department. Due to the fact that the features included in hearing aids is related to the size and form-factor of the device, the devices were separated for the feature analysis into two distinct categories: 1) Behind-the-ear (BTE) hearing aids and Receiver-in-ear (RIC) hearing aids; and 2) Custom hearing aids (ITE, ITC & CIC).

Several selection criteria were applied to determine the list of hearing aids to be included in the review. First, the devices had to be approved and have been provided as a fully-subsidised device under the Program during the period for which data were available. Second, at least 200 units of the device must have been supplied over that period, which was selected as a threshold to focus on devices that are representative of the majority of devices being provided to clients of the Program. Third, there must be publicly-available technical data sheets for the devices from the manufacturer.

The final list of hearing aids comprised 20 BTE/RIC hearing aids and 11 custom hearing aids. The list accounted for approximately 92% of the total number of hearing aids supplied under the Program over the 12-month period in each of the two device categories.

Table 4: List of hearing aids selected for scoping review

Device category	Manufacturer	Model
BTE and RIC hearing aids	Hearing Australia	XC388-DWH XC367-DW XC377-DW
	Oticon	Jet 1 BTE 85 Jet 1 BTE PP Zircon 2 miniBTE T
	Resound	Key 3 KE388-DWH Key 3 KE398-DW KE367-DW KE377-DW
	Signia	Intuis M 4.1 Intuis P 4.1 Motion 13 BT 1nx BTE Motion 13 P BT 1nx
	Starkey	Livio 1000 BTE 13 Livio 1000 RIC 312
	Unitron	Stride B-UP 3

Device category	Manufacturer	Model
Custom hearing aids	Widex	DX Stride M 3
		Magnify 50 BTE 13D
		Magnify 50 BTE 312
	Hearing Australia	XC3ITC-DW
		XC3ITE-DW
	Oticon	Jet 1 ITC
		Jet 1 ITE
	Resound	Key 3 KE3ITC-DW
		Key 3 KE3ITE-DW
	Signia	Insio ITC 1nx
		Insio ITE 1nx
	Unitron	DX Insera W 312 DIRECTIONAL 3
		Insera B3-312
	Widex	Magnify 50 XP

Summary of prevalence of features

Each hearing aid included in the review was assessed to determine if it contained each of the features listed in the lexicon of hearing aid features previously developed by NAL for the Department (see Section A6). The initial review of features used publicly available technical data sheets. Manufacturers were then consulted to provide feedback and confirm the accuracy of the feature assessment.

All six manufacturers responded to the request for feedback on the review of features. Five out of the six manufacturers provided feedback highlighting differences between the results of the initial review and the features that are actually present in their devices. In the majority of these cases, the discrepancies related to hearing aid features that were present in their device(s) but had not been identified as present based on the publicly available data sheets. After incorporating the manufacturer feedback, the results of the assessment were used to determine the prevalence of each feature within hearing aids supplied under the Program for each of the two device categories. The summary of feature availability following manufacturer feedback is shown in Table 5.

Table 5: Prevalence of each feature expressed as a percentage of devices under assessment supplied by the Program in 2022-23

Device category	Feature	Prevalence
BTE and RIC hearing aids	Automatic directional microphone	100%
	Adaptive directional microphone	91%
	Binaural directionality	0%
	Frequency lowering	59%
	Music	58%
	Adaptive noise reduction	100%
	Feedback prevention	100%
	Soft noise reduction	92%
	Reverberation reduction	9%
	Wind noise reduction	67%

Device category	Feature	Prevalence
	Tinnitus therapy	75%
	Acclimatization	100%
	Ear-to-ear communication	100%
	Accessory connectivity	100%
	App connectivity	100%
	Remote clinician adjustments	100%
	Phone streaming	96%
	Data logging	100%
	Transient noise reduction	22%
	Smart personalisation	0%
Custom hearing aids	Automatic directional microphone	81%
	Adaptive directional microphone	81%
	Binaural directionality	0%
	Frequency lowering	44%
	Music	48%
	Adaptive noise reduction	100%
	Feedback prevention	100%
	Soft noise reduction	90%
	Reverberation reduction	0%
	Wind noise reduction	77%
	Tinnitus therapy	81%
	Acclimatization	100%
	Ear-to-ear communication	100%
	Accessory connectivity	100%
	App connectivity	100%
	Remote clinician adjustments	100%
	Phone streaming	89%
	Data logging	100%
	Transient noise reduction	25%
	Smart personalisation	0%

Considerations for developing minimum specifications for hearing aids

Key considerations

The recommended minimum specifications were developed to seek a balance between the practical realities of current hearing aid technology with the evolving needs and expectations of hearing aid users. Several key considerations guided the development of the minimum specifications:

- **Prevalence in current hearing aids:** Features and capabilities that are commonly available in hearing aids currently provided through the Program should be included in the minimum specification
- **Ensuring acceptable real-world performance:** The specifications should prioritise capabilities and functions that are critical to achieving key performance outcomes, such as improved audibility, sound quality, comfort, usability, and longevity of the devices
- **Consumer desirability:** The specifications should align with consumer needs and preferences, seeking to include features and capabilities that are most valued and desirable from the consumer perspective
- **Achievability with current technology:** The specifications should be achievable by manufacturers within the confines of current hearing aid technology
- **Support for future innovation:** The specifications should not impede continued innovation in the hearing aid industry.

Thus, the overall intent of the recommendations is to provide a solid baseline for an acceptable level of performance and user experience, while leaving room for new technologies, features and functionality to emerge over time.

Client choice and access requirements

Receiver-In-Canal (RIC) hearing aids: Global market data indicates that Australia is lagging behind other markets in the uptake of Receiver-In-Canal (RIC) hearing aids, which are considered superior technology to behind-the-ear hearing aids. For example, in the United States, RICs accounted for 81% of supplied hearing aids in 2021 (Statistica, 2022), while five out of the six manufacturers included in our scoping review did not offer a RIC model on the fully-subsidised device schedule.

RIC hearing aids are also generally preferred over Behind-The-Ear (BTE) models due to smaller form factor and improved sound quality (Alworth et al., 2010). Given the superior technology and consumer preference for RIC form factors, the proposed minimum specifications now includes requirements for manufacturers to include RIC hearing aids in their submissions. This recommendation is intended to better align the Program's offerings with the evolving preferences and trends observed in other major hearing aid markets around the world.

Key conclusion:

The minimum specification should include a requirement that manufacturers who wish to list any hearing aid device must list at least one RIC hearing aid on the same device schedule.

Rechargeable hearing aids: According to the MarkeTrak 2022 Survey, rechargeable batteries are the most positively impactful feature for in-person fitted hearing aid users (Picou, 2022). However, our scoping review found that the Program did not supply any fully-subsidised rechargeable hearing aids during the 2022-2023 period. Given the clear importance of rechargeable hearing aids, the proposed minimum specifications now include requirements for manufacturers to include rechargeable options, particularly in the BTE/RIC category. Currently, there are a wide range of rechargeable BTE/RIC hearing aids available on the market. In contrast, fewer manufacturers offer rechargeable battery options in the custom hearing aid category. Consequently, the new criteria only apply to the BTE/RIC categories for now.

Note that this recommendation only relates to the internal battery and does not imply that a means of charging the battery is to be provided free-of-charge with the device. The provision of a charging method is a separate consideration for the Program. Future reviews of the Program should re-evaluate the need to expand the rechargeable criteria to custom hearing aids

Key conclusion:

The minimum specification should include a requirement that manufacturers who wish to list a BTE or RIC device must list at least one rechargeable hearing aid in the same category. This recommendation does not extend to the provision of a battery charger, as well, as technology continues to evolve.

Legacy technologies and features: Careful consideration was also given to hearing aid technologies that are seeing a decline in usage or being supplanted by newer innovations. For example, features like telecoil and manual controls have become increasingly less common as core features in modern hearing aids as wireless connectivity, automatic volume adjustment, and app-based controls have become the standard offering. However, there remains a segment of hearing aid users who still rely on these established technologies.

To balance supporting these legacy features while also encouraging technological advancement, the proposed minimum specification now requires that if a manufacturer wishes to list a hearing aid model that does not include a telecoil, they must already have at least one device listed in the same device category that does support telecoil. Similarly, if a manufacturer wishes to list a hearing aid model in the BTE or RIC device categories that does not include manual controls, they must already have at least one device listed in the same device category that does have manual controls. This approach ensures continued access for users who depend on these older technologies, while still allowing manufacturers the flexibility to innovate and offer hearing aids without them as newer solutions gain wider adoption.

Key conclusion:

The minimum specification should include a requirement that manufacturers include at least one device in relevant hearing aid categories that supports telecoil and manual controls.

Other requirements

Battery specifications: The review identified a need to establish minimum specifications for both disposable and rechargeable hearing aid batteries. Currently, most manufacturers provide estimates of battery life in their technical data sheets. However, these estimates can vary for many reasons including the methodology used to estimate battery life and the assumptions made about the proportion of use that involves streaming, as wireless streaming technologies tend to have higher power requirements than typical non-streaming hearing aid use. To address this, some manufacturers now indicate the time or proportion of time spent streaming when reporting their battery life estimates.

To develop appropriate and achievable minimum battery life specifications, the review collected manufacturer battery life data across a wide range of hearing aid products and battery types. While there was some variance, likely due to differences in how manufacturers estimate typical usage, the data suggested that hearing aids on the Australian market are generally optimised for efficient power consumption.

The proposed minimum battery life specifications take into account the differences between battery types and require manufacturer battery life estimates to include a minimum of 25% wireless streaming usage. This is intended to increase transparency and consistency in how manufacturers report their battery life estimates.

For rechargeable hearing aid batteries, the review determined that a reasonable minimum specification is for the batteries to last at least a full day of typical use on a single charge. This aligns with the battery life performance of current rechargeable hearing aids available on the market. Additionally, the charging time for rechargeable batteries should allow for a fully discharged battery to reach a full charge during a typical overnight period. Fast charging, the ability to quickly recharge a rechargeable battery over a short period of time, was also considered. However, not all hearing aid manufacturers currently offer fast charging capability, and it is typically only available on premium models. As a result, fast charging criteria were omitted from the proposed minimum specifications. Finally, the lifespan of rechargeable batteries used in hearing aids should meet the standards of current rechargeable battery technologies.

The recommendations for the minimum specifications for rechargeable hearing aid batteries now include requirements for battery life, charge time, and overall lifespan. These specifications are designed to align with standard hearing aid usage patterns, as well as the capabilities of rechargeable technologies used in hearing aids currently available in the Australian market.

Key conclusion:

The minimum specification should include criteria for battery life, rechargeable battery charging time, and rechargeable battery lifespan.

Performance levels for specific features: Each hearing aid feature was evaluated to determine if a minimum performance specification was necessary to establish as part of the minimum specification, and if so whether it was feasible to determine. For some capabilities, specifically directional microphones and adaptive noise reduction, it was deemed both feasible and appropriate to set minimum performance specifications to ensure a consistent baseline level of performance across all devices provided under the Program. In establishing these criteria, the team drew upon manufacturer data as well as the wider scientific literature to identify achievable and appropriate performance indicators.

Key conclusion:

The minimum specification should include specific performance criteria for directional microphones and adaptive noise reduction.

Wireless broadcast technology: Many hearing aids now offer wireless connectivity, such as Auracast using Bluetooth Low Energy Audio, as an alternative to traditional telecoil technology for connecting to assistive listening systems. This technology can provide improved sound quality and convenience compared to telecoils. However, wireless connectivity standards for hearing aids are still emerging and evolving rapidly. As a result, the current minimum specification does not include criteria for wireless alternatives to telecoils, but this area of the minimum specifications should be reviewed as this new technology becomes adopted.

Key conclusion:

Future updates to the specification should re-evaluate the need for requirements related to wireless broadcast technology as this technology becomes more standardised and adopted as the alternative to telecoils.

Recommendations for feature requirements

Table 4 lists the features that are recommended as a requirement for all subsidised devices listed in device categories for Hearing Aids along with information about the rationale for their inclusion in the minimum specification. It is recommended that certain features must also meet the minimum performance specifications, which are listed in Table 5. Definitions for all features are provided in Section A6 of Appendix 1 of this report.

Table 6: Recommended minimum specifications for features of devices listed in device categories for Hearing Aids

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)	
Hearing Aids (HA)	Minimum specification	Rationale (Features available in contemporary fully-subsidised devices supplied under the Program)

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)	
HA BTE and HA RIC	<ul style="list-style-type: none"> Automatic directional microphone 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Adaptive directional microphone* 	<ul style="list-style-type: none"> Present in 91%
	<ul style="list-style-type: none"> Adaptive noise reduction* 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Feedback prevention* 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Soft noise reduction* 	<ul style="list-style-type: none"> Present in 92%
	<ul style="list-style-type: none"> Ear-to-ear communication 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Accessory connectivity 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> App connectivity 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Remote clinician adjustments 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Phone streaming 	<ul style="list-style-type: none"> Present in 96%
HA C and HA NC (excluding CIC and IIC)	<ul style="list-style-type: none"> Automatic directional microphone 	<ul style="list-style-type: none"> Present in 81% Improves speech understanding in noise (Gnewikow et al., 2009).
	<ul style="list-style-type: none"> Adaptive directional 	<ul style="list-style-type: none"> Present in 81%
	<ul style="list-style-type: none"> Adaptive noise reduction* 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Feedback prevention* 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Soft noise reduction* 	<ul style="list-style-type: none"> Present in 90%
	<ul style="list-style-type: none"> Ear-to-ear communication 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Accessory connectivity 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Remote clinician adjustments 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> App connectivity 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Phone streaming 	<ul style="list-style-type: none"> Present in 89% Rated as 3rd most positively impactful feature (behind rechargeable and volume control) for in-person fitted HA users (Picou, 2022).
HA C and HA NC (CIC and IIC only)	<ul style="list-style-type: none"> Data logging 	<ul style="list-style-type: none"> Present in 100%
	<ul style="list-style-type: none"> Adaptive noise reduction* 	<ul style="list-style-type: none"> CIC and IIC feature requirements are limited by form factor. These devices typically do not have enough space to accommodate multiple microphones or current wireless technologies. All features were present in >90%
	<ul style="list-style-type: none"> Feedback prevention* 	
	<ul style="list-style-type: none"> Soft noise reduction* 	
	<ul style="list-style-type: none"> Data logging 	

* Feature must meet minimum performance specification listed in Table 6.

Table 7: Recommendations for minimum performance specifications for Hearing Aid features

Feature	Minimum performance definition	Minimum performance requirement	Rationale/evidence
Adaptive Directional microphone	Capable of achieving a minimum Articulation-Index-weighted Directivity Index (AI-DI)	<ul style="list-style-type: none"> • 3 dB for closed fittings or vents up to 2mm diameter • 2 dB for open fittings or vents >2mm diameter 	<ul style="list-style-type: none"> • AI-DI is an indicator of directionality that emphasises the frequencies most important to speech understanding. • These values represent what modern free-to-client devices can achieve (Ricketts, 2000). • These values are equivalent to a directional advantage that provides measurable and perceivable improvements in speech understanding (Magnusson et al., 2013).
Adaptive noise reduction	Capable of achieving a minimum improvement in signal-to-noise ratio (SNR)	5 dB	<ul style="list-style-type: none"> • This criterion is achievable in modern free-to-client devices. • Most hearing aid users prefer more aggressive adaptive noise reduction settings (Wong et al., 2018).
Feedback prevention	Capable of achieving a minimum additional stable gain before feedback	10 dB	<ul style="list-style-type: none"> • This value represents what modern free-to-client devices can achieve (Marcum et al., 2018).
Soft noise reduction	Capable of achieving a minimum attenuation of noise at or below the levels of soft speech	3 dB	<ul style="list-style-type: none"> • This value is representative of the minimum perceptible changes in noise levels (McShefferty et al., 2015).

Recommendations for client choice and access requirements

It is recommended that the following additional requirements are placed on the listing of devices under the Program's device schedules. Each requirement is described alongside the evidence/rational for its inclusion in the minimum specification. Note that these requirements are not affected by whether a supplement (+R, +HP) is applied to a device.

Area	Recommended Requirement	Evidence/Rationale
Receiver in the canal (RIC) hearing aid	A Supplier who wishes to list a Hearing Aid (HA) device in any of the hearing aid device categories other than Receiver in the canal (RIC) must already have a device listed in the Receiver in the canal (RIC) hearing aid device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices).	<ul style="list-style-type: none"> The intent of this requirement is to ensure that RIC HAs are available under the Program. Where suitable, RICs are preferred over BTEs due to smaller form factor and improved sound quality (Alworth et al., 2010). Australia is lagging behind other markets in the uptake of RIC HAs; E.g. In the USA, RICs accounted for 81% of supplied devices in 2021 (Statistica, 2022).
Rechargeable hearing devices	A Supplier who wishes to list a Hearing Aid (HA) device in either the Behind the ear (BTE) or Receiver in the canal (RIC) categories must already have a device with a rechargeable battery listed in the same device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices). This recommendation only relates to the internal battery and does not extend to the provision of a battery charger.	<ul style="list-style-type: none"> The intent of this requirement is to ensure that rechargeable hearing aids are supported and available under the hearing services program. Rechargeable hearing aids were rated as the #1 most positively impactful feature for in-person fitted HA users (Picou, 2022). At present, rechargeable hearing aids are widely available in the BTE/RIC categories. Many manufacturers do not have rechargeable custom devices on the market (or they are reserved for high-level devices only).
Telecoil	A Supplier who wishes to list a Hearing Aid (HA) device in a hearing aid device category other than HA NC must already have a device that incorporates an effective telecoil and means for enabling the telecoil in the same device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices). Where it is not possible for Supplier to list a device that incorporates an effective telecoil and means for enabling the telecoil, a Supplier must list a device in the same device category on the same device schedule that includes an accessory, free of charge, that accommodates this requirement.	<ul style="list-style-type: none"> The intent of this requirement is to continue to support the provision of telecoils under the Program. While emerging technologies (e.g. Auracast) have the potential to replace telecoil in the future, such technologies have not yet been widely adopted or recognised as acceptable options when it comes to fulfilling the accessibility requirements where required by legislation (e.g. building codes and transportation systems). Induction loop infrastructure is still being provisioned in present day commercial construction projects.
Manual controls	A Supplier who wishes to list a Hearing Aid (HA) device in either the Behind the ear (BTE) or Receiver in the canal (RIC) categories must already have a device that	<ul style="list-style-type: none"> The intent of this requirement is to ensure that hearing aid users continue to have access to a manual volume control under the hearing services program.

Area	Recommended Requirement	Evidence/Rationale
	incorporates a means to adjust the volume manually using a physical control on the device listed in the same device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices).	<ul style="list-style-type: none"> Manual volume control was rated as the #2 most positively impactful feature for in-person fitted HA users (Picou, 2022).

Recommendations for technical requirements

In addition to recommendations about the features that should be available in subsidised Hearing Aid devices provided under the Program, it was determined that additional technical requirements were necessary to specify in order that those Hearing Aids could fulfil the clinical requirements for such devices and be suitable for use in the context of the Program's requirements as set out in the schedule of service items and fees. Table 7 lists the recommended technical requirements alongside the evidence/rational for their inclusion in the minimum specifications.

Table 8: Recommendations for technical Requirements for devices listed in Hearing Aid device categories

Category	Technical Requirements
Acoustic output and adjustability	Evidence/Rationale
<ul style="list-style-type: none"> The fitter must be able to adjust the gain at a minimum of 5 frequencies (250, 500, 1000, 2000, and 4000 Hz) and at a minimum of 3 input sound pressure levels (at least one <55 dB SPL, at least one between 60-70 dB SPL, at least one >75 dB SPL) with sufficient precision to enable the device to be programmed to and verified against a prescriptive target The fitter must be able to adjust the maximum output level (OSPL90) at a minimum of 5 frequencies (250, 500, 1000, 2000, and 4000 Hz) and over a range of adjustment wide enough that the device produces adequate loudness sensation while avoiding loudness discomfort The device must have a minimum operating bandwidth of 200 Hz to 4000 Hz 	<ul style="list-style-type: none"> This terminology has been used as it is consistent with the related legislation (schedule of service item as fees) that still requires verification against prescriptive target.
Gain and compression	Evidence/Rationale
<ul style="list-style-type: none"> The device must be capable of dynamically adjusting the gain it applies to incoming sounds to: <ul style="list-style-type: none"> match the intended output dynamic range at different frequencies as specified by a prescriptive target mitigate loudness discomfort and distortion 	<ul style="list-style-type: none"> These criteria crucially support low-level speech intelligibility, and acceptable distortion and comfort in noisy environments. Most current subsidized devices satisfy these criteria using wide dynamic range compression technology. The criteria allow for submissions that use alternative solutions, if appropriate.
Distortion and noise	Evidence/Rationale

Category	Technical Requirements
<ul style="list-style-type: none"> The harmonic distortion (HD)¹ must not exceed the following values: <ul style="list-style-type: none"> 7% at 500 Hz with 70 dB input SPL, 7% at 800 Hz with 70 dB input SPL, 3% at 1600 Hz with 65 dB input SPL. The Equivalent Input Noise (EIN)² must not exceed 31 dB SPL. 	<ul style="list-style-type: none"> These values represent what modern free-to-client devices (including high-powered devices, which produce more harmonic distortion) can achieve. Manufacturers are generally already reporting these THD and EIN values on their data sheets.
Durability and lifespan	Evidence/Rationale
<ul style="list-style-type: none"> The device must be capable of operating while being exposed to levels of moisture, temperature, humidity and dust that would be expected to arise from typical usage in the Australian climate 	<ul style="list-style-type: none"> These are reasonable expectations for modern hearing aids and reflect the considerations specific to their use in Australia.
Battery life	Evidence/Rationale
<ul style="list-style-type: none"> The supplier must provide estimations of battery life for typical use within publicly available data sheets, and estimates should indicate the proportion of time allocated to wireless streaming For hearing aids with non-rechargeable batteries, the minimum battery life required under typical usage conditions (including a minimum of 25% wireless streaming) is: <ul style="list-style-type: none"> Type 10: 48 hours Type 312: 48 hours Type 13: 80 hours Type 675: 80 hours For hearing aids with rechargeable batteries, the minimum specifications for battery life under typical usage conditions (including a minimum of 25% wireless streaming), charging time, and lifespan of the rechargeable battery are: <ul style="list-style-type: none"> Minimum battery life: 16 hours per charge Maximum charging time: 4 hours from fully discharged to fully charged Minimum battery lifespan: 80% of original runtime after 2 years of regular use, or 80% of battery capacity after 2 years of regular use 	<ul style="list-style-type: none"> The battery life requirements are representative of modern free-to-client devices and would be satisfied by hearing aids currently scheduled under the hearing services program. It is a reasonable expectation for rechargeable batteries to last a full day of typical use and to be fully charged overnight. Rechargeable battery lifespan criterion is representative of what present-day rechargeable battery technologies can achieve.

¹ As defined in IEC60118-0:2022 or ANSI/ASA S3.22-2014 (R2020)

Section 5: Recommendations for assistive listening devices

Scoping Review

The scoping review determined the prevalence of various assistive listening device features in devices currently subsidised under the Program. This review was based on the Program Schedule and supply data across a period of 12 months (2022-2023), as provided by the Department.

Although all assistive listening devices on the Schedule are categorised as such, for the purposes of clarity and accuracy in determining relevant features this review separated ALDs into sub-categories of intended use. These sub-categories were TV/Music Listening Systems (ALD TM), Personal Sound Amplifiers (ALD PSA), Personal Sound Amplifiers with TV/Music listening capability (PSA +TM), and Supported Self-Fitting hearing devices (ALD SSF). These categories are generally aligned with categories that appear on the DVA RAP Schedule, which may provide consistency useful to manufacturers and hearing providers who engage regularly with both programs.

The list of ALDs reviewed included all devices approved on the Program's schedules, whether they were or were not supplied under the Program in the period from 2022-2023. This amounted to 32 devices from 10 manufacturers (Table 8). Of the 32 devices, 17 were supplied at least once and 15 were not supplied during the period from 2022-2023.

The list of devices included for review were further categorised into their assigned sub-categories, comprising of 16 TV/Music Listening Systems, 13 Personal Sound Amplifiers, 2 Personal Sound Amplifiers with TV/Music listening capability, and 1 Supported Self-Fitting Hearing Device.

Table 9: List of ALDs included in the scoping review

Category	Manufacturer	Model
TV/Music Listening Systems	Audeara	<ul style="list-style-type: none"> A01+BT01 TV Bundle A02+BT02 TV Bundle
	Humantechnik	<ul style="list-style-type: none"> EARIS A-4100-0 Premium TV Listening System EARIS XS A-4102-0 TV Listening System - Underchin Style EARIS XS A-4112-0 TV Listening System Pocket Receiver Style SONUMAXX 2.4 TV Listening System Tiviton TV Listening System / Personal Amplifier / DAB+ Radio Underchin Style
	Oricom	<ul style="list-style-type: none"> TV 7300 Stereo Headset (stethoset)
	Sennheiser	<ul style="list-style-type: none"> Flex 5000 RR Flex RS195 Headphones RS5000 Stethoset Set 860 TV TVS 200 Earbuds TVS 200 Set

Category	Manufacturer	Model
	Silent Safaris	<ul style="list-style-type: none"> SS-H03 Wireless Headphone System
Personal Sound Amplifiers	BeHear	<ul style="list-style-type: none"> ACCESS II NOW PROXY SMARTO
	Bellman	<ul style="list-style-type: none"> Audio Maxi Pro Personal Listener w/earbuds Audio Maxi Pro Personal Listener w/headphones Audio Mino Personal Listener w/earbuds Audio Mino Personal Listener w/headphones
	Geemarc	<ul style="list-style-type: none"> CLA9 Personal Amplifier
	Humantechnik	<ul style="list-style-type: none"> Crescendo 60 Personal Amplifier
	Williams Sound	<ul style="list-style-type: none"> PockeTalker 2.0 PockeTalker D1 – Headphone PockeTalker Ultra EH
Personal Sound Amplifiers with TV/Music	Bellman	<ul style="list-style-type: none"> Audio Maxi Pro TV System w/Earbuds Audio Maxi Pro TV System w/Headphones
Supported Self-Fitting Hearing Devices	Nuheara	<ul style="list-style-type: none"> IQbuds2 MAX

Summary of prevalence of features

Table 10 lists the features of ALDs using the lexicon of hearing device features developed previously by NAL for the Department (see Section A6) based on the publicly available marketing materials, manuals, and technical data sheets.

Table 10: Prevalence of features within assistive listening devices expressed as a percentage of scheduled devices under assessment.

Category	Feature	Prevalence
TV/Music Hearing Systems	Active Noise Cancellation	0%
	Bluetooth	44%
	Custom Programs	6%
	Direct Audio Input (DAI)	94%
	Directional Microphones	0%
	Earbuds	38%
	External Speaker	0%
	Frequency Shaping	88%
	Headphones	19%
	Hearing Assessment	6%
	In-App Control	25%
	Listen-Through	19%

Category	Feature	Prevalence
	Mono (Monaural)	13%
	Neck Loop	0%
	Noise Therapy	0%
	Phone Connectivity (wireless)	13%
	Rechargeability	100%
	Remote Control	6%
	Remote Microphone	19%
	Self-Fitting	0%
	Shaker-Vibration	0%
	Speech Slow	0%
	Stereo (Binaural)	100%
	Stereo Balance Control	50%
	Stethoset	44%
	Telecoil	0%
	Volume Control	100%
	Wide Dynamic Range Compression	0%
	Wind Protection	0%
Personal Sound Amplifier	Active Noise Cancellation	31%
	Bluetooth	46%
	Custom Programs	0%
	Direct Audio Input (DAI)	38%
	Directional Microphones	8%
	Earbuds	54%
	External Speaker	8%
	Frequency Shaping	100%
	Headphones	46%
	Hearing Assessment	31%
	In-App Control	31%
	Listen-Through	23%
	Mono (Monaural)	46%
	Neck Loop	15%
	Noise Therapy	31%
	Phone Connectivity (wireless)	31%
	Rechargeability	77%
	Remote Control	0%
	Remote Microphone	38%
	Self-Fitting	0%
	Shaker-Vibration	8%
	Speech Slow	31%

Category	Feature	Prevalence
	Stereo (Binaural)	100%
	Stereo Balance Control	8%
	Stethoset	15%
	Telecoil	38%
	Volume Control	100%
	Wide Dynamic Range Compression	0%
	Wind Protection	23%
Personal Sound Amplifier + TV/Music	Active Noise Cancellation	0%
	Bluetooth	100%
	Custom Programs	0%
	Direct Audio Input (DAI)	100%
	Directional Microphones	0%
	Earbuds	50%
	External Speaker	0%
	Frequency Shaping	0%
	Headphones	50%
	Hearing Assessment	0%
	In-App Control	0%
	Listen-Through	0%
	Mono (Monaural)	0%
	Neck Loop	0%
	Noise Therapy	0%
	Phone Connectivity (wireless)	0%
	Rechargeability	100%
	Remote Control	0%
	Remote Microphone	0%
	Self-Fitting	0%
	Shaker-Vibration	0%
	Speech Slow	0%
	Stereo (Binaural)	100%
	Stereo Balance Control	0%
	Stethoset	0%
	Telecoil	0%
	Volume Control	100%
	Wide Dynamic Range Compression	0%
	Wind Protection	0%
Supported Self-Fitting Hearing Devices	Active Noise Cancellation	100%
	Bluetooth	100%

Category	Feature	Prevalence
	Custom Programs	100%
	Direct Audio Input (DAI)	0%
	Directional Microphones	100%
	Earbuds	100%
	External Speaker	0%
	Frequency Shaping	100%
	Headphones	0%
	Hearing Assessment	100%
	In-App Control	100%
	Listen-Through	100%
	Mono (Monaural)	0%
	Neck Loop	0%
	Noise Therapy	100%
	Phone Connectivity (wireless)	100%
	Rechargeability	100%
	Remote Control	0%
	Remote Microphone	0%
	Self-Fitting	100%
	Shaker-Vibration	0%
	Speech Slow	0%
	Stereo (Binaural)	100%
	Stereo Balance Control	0%
	Stethoset	0%
	Telecoil	0%
	Volume Control	100%
	Wide Dynamic Range Compression	100%
	Wind Protection	0%

Considerations for developing minimum specifications for ALDs

Key considerations

The new minimum specifications seek to provide reasonable baseline feature requirements for devices within each category of devices. Several key considerations guided the development of these minimum specifications:

- **Prevalence in current devices:** The recommendations should encompass the features and capabilities that are commonly available in assistive listening devices currently provided through the Program, within each device category.
- **Achievability with current technology:** Manufacturers should be able to meet the requirements within the confines of current consumer and assistive listening device technologies, specific to each category of devices.
- **Support for future innovation:** The minimum specifications were designed to allow reasonable space for innovation and to allow for emerging technologies to be made available. This is particularly necessary to accommodate the anticipated increase in the variety of devices available within the Supported Self-Fitting category and how form factor, programming capabilities, and power source options may vary among future devices.

Supported Self-Fitting (ALD SSF) Hearing Devices

Due to potential market growth of self-fitting/direct-to-consumer-style hearing devices (which, for the purposes of the Program, have been designated as “Supported Self-Fitting Hearing Devices”), it has become evident within the scope of this review to provide advice and foresight on how to best define and specify these devices both in terms of how such devices should be categorised and in terms of their minimum feature requirements. Although the distinction between self-fitting devices and prescription hearing aids is straightforward to define at the time of this report, the distinction amongst different self-fitting devices is, in general, less clear. As a greater selection of consumer devices with enhanced listening capabilities become available, it may be important to provide some distinction between their capabilities and intended uses in how they are categorised and in what features are required under the minimum specifications.

The current landscape of these devices indicates that they may have widely varying procedures for determining an appropriate amplification profile. These “self-fitting” procedures may consist of the user simply choosing a preferred preset, entering a pre-existing audiogram, or undertaking a guided listening exercise to determine an appropriate amplification preset. These in-situ hearing assessments may at some time or in some instances be intended to provide amplification based on prescription targets, with or without a verification procedure or the guidance of a hearing professional.

For the purposes of the Program requirements, the designation of these devices as “Supported Self-Fitting” ALDs is an important distinction in that they are not designed to be provided according to the requirements for hearing aids set out in the schedule of service items and fees. For example, the relevant fitting activities are not required to be performed and documented by a Qualified Practitioner, nor are they required to be verified against a prescriptive target. Should the requirements around the provision of hearing aids change in the future, as currently documented in the schedule of service items and fees, the Department may wish to review whether self-fitting devices are still appropriately categorised as ALDs.

Key consideration:

As ALD SSF technology continues to advance, it is recommended that ongoing review of this device category is undertaken to ensure their appropriate categorisation as either ALDs or Hearing Aids, and which requirements around their provision under the Program should apply.

Recommended for feature requirements

Table 10 lists the recommendations for which features of ALDs should be included under the revised minimum specifications, along with the rationale/evidence for their inclusion. Definitions for all features are provided in Section A6 of Appendix 1 of this report.

Table 10: Recommended minimum specifications for features of devices listed in device categories for Assistive Listening Devices

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)	Rationale/Evidence/% devices supplied under HSP
Assistive Listening Devices (ALD)	Feature	Rationale
ALD TM	<ul style="list-style-type: none"> Rechargeability Stereo/binaural sound Volume control 	<ul style="list-style-type: none"> Present in 100% of devices of this kind supplied under the Program
ALD PS	<ul style="list-style-type: none"> Rechargeability Stereo/binaural sound Volume control Frequency shaping 	<ul style="list-style-type: none"> Present in 100% of devices of this kind supplied under the Program
ALD PS +TM	<ul style="list-style-type: none"> Rechargeability Stereo/binaural sound Volume control Frequency shaping Direct audio input Accessory connectivity 	<ul style="list-style-type: none"> Present in 100% of devices of this kind supplied under the Program
ALD SSF	<ul style="list-style-type: none"> Stereo/binaural sound Volume Control Frequency shaping Noise reduction Directional microphones Accessory connectivity Phone Streaming Custom programs App connectivity Self-fitting 	<ul style="list-style-type: none"> Present in 100% of devices of this kind supplied under the Program (and in similar devices recently introduced into the Australian market but not yet listed on the Program's schedules)

Recommendations for technical requirements

Given the heterogeneity in the form factor and technologies that different manufacturers use in their devices, no recommendations for technical requirements are made.

Section 6: Minimum Specifications for Cochlear Implant Sound Processors

Scoping review

The scoping review determined the prevalence of various cochlear implant features in cochlear implant (CI) devices currently available in Australia. This review was based on CI devices approved under the Therapeutic Goods Administration (TGA) as an approved sound processor or Class III medical device. The data on feature availability was separated into two distinct categories of devices: 1) CI with a Behind-the-ear (BTE) processor, and 2) CI with an Off-the-ear (OTE) processor.

The selection criteria applied to determine the list of CI sound processors included for review included that they were TGA approved, listed on Australian Government Department of Health and Aged Care Prosthesis List, and it was possible to obtain publicly available technical data sheets describing the features of these devices.

The final list of CI sound processors consisted of five BTE CIs from Advanced Bionics, Cochlear Ltd, and MED-EL, and two OTE CIs from Cochlear Ltd and MED-EL (Table 11)

Table 11: List of cochlear implant sound processors selected for scoping review

Category	Manufacturer	Model
CI with BTE processor	Advanced Bionics	Sky CI M90 Naida CI M90
	Cochlear Ltd	Nucleus 7 Nucleus 8
	MED-EL	Sonnet 2
CI with OTE processor	Cochlear Ltd	Kanso 2
	MED-EL	Rondo 3

Summary of prevalence of features

CI sound processor features included in the review were derived largely from the lexicon of hearing aid features developed by NAL previously for the Department (see Section A6) with additions based on CI specific needs. Each sound processor was assessed for the inclusion of each feature using the publicly available technical data sheets or websites. Manufacturers were then consulted to provide feedback and confirm the accuracy of the assessment.

All three manufacturers responded to our request for feedback. All three manufacturers provided feedback highlighting differences between the features we assessed and those present in their devices. In most of these cases, the discrepancies related to features that were present but not specified on the relevant publicly available data sheets. After incorporating the manufacturer feedback, the results of the assessment were used to determine the prevalence of each feature within cochlear implant sound processors for each of the two categories (Table 12).

Table 12: Prevalence of features within cochlear implants expressed as a percentage of devices under assessment

Category	Feature	Prevalence
CI with BTE processor	Accessory connectivity	100%
	Adaptive directional microphones	100%
	Adaptive noise reduction	100%
	App connectivity	100%
	Automatic directional microphones	100%
	Automatic environment-based adjustments	100%
	Bilateral synchronisation	40%
	Binaural directionality	40%
	Canal microphones	40%
	Colour Options	100%
	Customisable Program Slots	100%
	Data Logging	100%
	Electric-Acoustic Stimulation	100%
	Environmental classifiers	100%
	Fixed directional microphones	100%
	GPS Tracking	60%
	Implant backwards compatibility	100%
	Microphone Check	100%
	Omni directional microphones	100%
	On-device control	80%
	On-site firmware updates	100%
	Phone assistive technology	80%
	Phone streaming	100%
	Physical Remote Control	100%
	Real-time MAP adjustment	80%
	Rechargeability	100%
	Remote firmware updates	60%
	Remote programming	100%
	Retention Accessories	100%
	Reverberation Reduction	40%
	Security and Tamper Resistance	100%
	Soft noise reduction	100%
	Telecoil	100%
	Transient noise reduction	100%
	Visual Alerts	100%
	Water and Dust Resistance	100%
	Water-safe accessories	100%
	Wide Dynamic Range Compression	100%
	Wind reduction features	100%

Category	Feature	Prevalence
CI with OTE processor	Wireless fitting	100%
	Zinc-Air Batteries	100%
	Accessory connectivity	100%
	Adaptive directional microphones	100%
	Adaptive noise reduction	100%
	App connectivity	100%
	Automatic directional microphones	100%
	Automatic environment-based adjustments	100%
	Bilateral synchronisation	0%
	Binaural directionality	0%
	Canal microphones	0%
	Colour Options	100%
	Customisable Program Slots	100%
	Data Logging	100%
	Electric-Acoustic Stimulation	0%
	Environmental classifiers	100%
	Fixed directional microphones	100%
	GPS Tracking	100%
	Implant backwards compatibility	50%
	Microphone Check	100%
	Omni directional microphones	100%
	On-device control	100%
	On-site firmware updates	100%
	Phone assistive technology	50%
	Phone streaming	50%
	Physical Remote Control	100%
	Real-time MAP adjustment	50%
	Rechargeability	100%
	Remote firmware updates	100%
	Remote programming	100%
	Retention Accessories	100%
	Reverberation Reduction	0%
	Security and Tamper Resistance	100%
	Soft noise reduction	100%
	Telecoil	100%
	Transient noise reduction	100%
	Visual Alerts	100%
	Water and Dust Resistance	100%
	Water-safe accessories	100%
	Wide Dynamic Range Compression	100%

Category	Feature	Prevalence
	Wind reduction features	100%
	Wireless fitting	100%
	Zinc-Air Batteries	0%

Recommendations for feature requirements

The recommendations for the minimum specification of features to be included in Cochlear Implant Sound Processors is shown in Table 13. Definitions for all features are provided in Section A6 of Appendix 1 of this report.

Table 13: Minimum specifications for features of devices listed in device categories for Cochlear Implant Sound Processors.

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)	Evidence/Rationale
BTE and BTE + EAS	<ul style="list-style-type: none"> Automatic directional microphones Automatic environment-based adjustments Adaptive directional microphones Adaptive noise reduction Soft noise reduction Accessory Connectivity App Connectivity Rechargeability Remote Clinician Adjustments Phone Streaming Data Logging 	<ul style="list-style-type: none"> Present in 100% of devices of this kind selected for review
OTE	<ul style="list-style-type: none"> Automatic directional microphones Automatic environment-based adjustments Adaptive directional microphones Adaptive noise reduction Soft noise reduction Accessory Connectivity App Connectivity Rechargeability Remote Clinician Adjustments Phone Streaming Data Logging 	<ul style="list-style-type: none"> Present in 100% of devices of this kind selected for review

Recommendations for technical requirements

Additional recommendations are made related to the technical requirements for cochlear implant sound processor devices. These requirements are listed in Table 14 along with the rationale for their inclusion.

Table 14: Technical Requirements for devices listed in Cochlear Implant Sound Processor device categories

Category	Technical Requirements	Rationale
Acoustic output and adjustability	<p>The fitter must be able to adjust the stimulation levels with sufficient precision to enable the device to be programmed to meet the needs of the user</p> <p>The fitter must be able to adjust the maximum stimulation level and over a range of adjustment wide enough that the device produces adequate loudness sensation while avoiding loudness discomfort</p>	Cochlear implant sound processors require sufficient controls to allow a clinician to fit the device to achieve good sensitivity to low sound levels while maintaining comfortable stimulation levels
Gain and compression	The device must be capable of dynamically adjusting the gain it applies to incoming sounds to mitigate loudness discomfort	Automatic control over stimulation levels is essential to avoid discomfort
Directional microphones	CISPs must provide clinicians and users with the functionality to alter the behaviour of the microphone(s) so that they can be set to Fixed directional (Maintains a consistent directivity pattern) and Omni directional (Intended to capture sounds from all directions) modes	The nature of cochlear implant sound processing means that control over the use of directional modes is essential in allowing the clinician to ensure appropriate access to sound for the wearer
Backwards compatibility	CISPs must be backward compatible with all cochlear implants from the same manufacturer that have been on the market in Australia in the 10 years prior to the device being submitted for listing on the Device Schedule	The long lifespan of the implantable component of cochlear implant systems means backwards compatibility is essential for sound processors
Internal microphone diagnostics	CISPs must enable clinicians and users to monitor both the functionality (e.g. microphone listening check or visual alerts) and sound quality (e.g. microphone listening check/self-diagnostics) of the internal microphone(s)	Unlike hearing aids, whose functionality can be checked by listening to them, additional features are required to confirm the full functionality of the sound processor

Section 7: Minimum Specifications for Bone Conduction and Middle Ear Devices

Scoping review

Bone conduction systems transmit sound vibrations directly through the bones of the skull to the cochlea (inner ear), bypassing the outer and middle ear. They can be non-surgical, utilizing a headband or similar device that rests against the skull and vibrates, or surgical, where a small abutment is implanted into the skull bone behind the ear to which an external sound processor attaches and transmits vibrations. Bone conduction sound processors are also used as part of middle-ear implant systems, which work by directly stimulating the ossicular chain (the bones in the middle ear) or the oval window within the middle ear space, requiring surgical implantation as they interface directly with the middle ear anatomy.

A scoping review was conducted to determine the prevalence of various device features in bone conduction sound processors. Devices were included in the review if they were registered with and approved by the Therapeutic Goods Administration (TGA), listed on Australian Government Department of Health and Aged Care Prosthesis List, and for which technical data sheets are available that provide information on the features of the devices. The devices were separated into two distinct categories based on the primary functionality of the sound processor: 1) sound processors that directly create vibrations via a mechanical transducer that is integral to the sound processor (including those that can be worn on an abutment or headband), and 2) sound processors that work in conjunction with a surgically implanted component of a bone conduction or middle ear implant system where the implantable component contains the mechanical transducer that creates the vibrations necessary for bone conduction.

The final list of bone conduction sound processors included the following manufacturers: Cochlear, MED-EL and Oticon. The list comprised of four bone conduction sound processors with integrated mechanical transducers (IMT) and two non-integrated mechanical transducer (NMT) bone conduction sound processors (Table 15).

Table 15: Bone conduction sound processors included in the scoping review.

Category	Manufacturer	Model
Bone Conduction Sound Processors Integrated mechanical transducer (IMT)	Cochlear Ltd.	Baha 5 SP (Superpower) Baha 6 Max
	Oticon	Ponto 5 SP (Superpower) Ponto 5 Mini
Bone Conduction Sound Processors Non-integrated mechanical transducer (NMT)	Cochlear Ltd	Osia
	Med-El	Samba 2

Summary of prevalence of features

Bone conduction sound processor features included in the review were summarised using an adapted version of the lexicon of hearing device features developed previously by NAL for the Department (see section A6), with additions based on bone conduction specific needs. Each sound processor was assessed for the inclusion of each feature using the

publicly available technical data sheets. Manufacturers were then consulted to provide feedback and confirm the accuracy of the assessment.

All three manufacturers responded to our request for feedback. All three manufacturers provided feedback highlighting differences between the features we assessed and those present in their devices. In most of these cases, the discrepancies related to features that were present but not specified on the relevant data sheets. After incorporating the manufacturer feedback, the results of the assessment were used to determine the prevalence of each feature within bone conduction sound processors for each of the two categories (Table 16).

Table 16: Prevalence of features in bone conduction sound processors expressed as a percentage of the devices assessed.

Category	Feature	Prevalence
Bone Conduction Sound Processors Integrated mechanical transducer (IMT)	Accessory connectivity	100%
	Adaptive directional microphones	100%
	Adaptive noise reduction	100%
	App Connectivity	100%
	Automatic directional microphones	100%
	Automatic environment-based adjustments	100%
	Bilateral synchronisation	50%
	Binaural directionality	50%
	Colour Options	100%
	Customisable Program Slots	100%
	Data Logging	100%
	Environmental classifiers	100%
	Feedback prevention	100%
	Fixed directional microphones	100%
	GPS Tracking	100%
	Omni directional microphones	100%
	On-device control	75%
	On-site firmware updates	100%
	Phone Streaming	100%
	Physical Remote Control	100%
	Rechargeability	25%
	Remote programming	50%
	Retention Accessories	100%
	Security and Tamper Resistance	100%
	Telecoil	100%
	Transient noise reduction	75%
	Visual Alerts	100%
	Water and Dust Resistance	100%
	Water-safe accessories	0%
	Wide Dynamic Range Compression	100%

Category	Feature	Prevalence
	Wind noise reduction	100%
	Wireless fitting	100%
	Zinc-Air Batteries	75%
Bone Conduction Sound Processors Non-integrated mechanical transducer (NMT)	Accessory connectivity	100%
	Adaptive directional microphones	100%
	Adaptive noise reduction	100%
	App Connectivity	100%
	Automatic directional microphones	100%
	Automatic environment-based adjustments	100%
	Bilateral synchronisation	50%
	Binaural directionality	0%
	Colour Options	100%
	Customisable Program Slots	100%
	Data Logging	100%
	Environmental classifiers	100%
	Feedback management	100%
	Fixed directional microphones	100%
	GPS Tracking	50%
	Omni directional microphones	100%
	On-device control	50%
	On-site firmware updates	50%
	Phone Streaming	100%
	Physical Remote Control	100%
	Rechargeability	0%
	Remote programming	0%
	Retention Accessories	100%
	Security and Tamper Resistance	100%
	Telecoil	50%
	Transient noise reduction	50%
	Visual Alerts	50%
	Water and Dust Resistance	100%
	Water-safe accessories	100%
	Wide Dynamic Range Compression	100%
	Wind reduction features	100%
	Wireless fitting	50%
	Zinc-Air Batteries	100%

Feature requirements

Table 17 lists the recommendations for the minimum specification of feature requirements for Bone Conduction Sound Processors provided under the Program together with the

rationale for inclusion in the minimum specifications. Definitions for all features are provided in Section A6 of Appendix 1 of this report.

Table 17: Recommendations for the minimum specifications for features of devices listed in device categories for Bone Conduction Sound Processors.

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)	Evidence/rationale
Bone Conduction Sound Processors Integrated mechanical transducer (IMT)	<ul style="list-style-type: none"> • Automatic directional microphones • Automatic environment-based adjustments • Adaptive directional microphones • Adaptive noise reduction • Accessory Connectivity • App Connectivity • Phone Streaming • Data Logging • Feedback cancellation 	<ul style="list-style-type: none"> • Present in 100% of devices of this kind selected for review
Bone Conduction Sound Processors Non-integrated mechanical transducer (NMT)	<ul style="list-style-type: none"> • Automatic directional microphones • Automatic environment-based adjustments • Adaptive directional microphones • Adaptive noise reduction • Accessory Connectivity • App Connectivity • Phone Streaming • Data Logging • Feedback cancellation 	<ul style="list-style-type: none"> • Present in 100% of devices of this kind selected for review

Recommendations for technical requirements

Recommendations for additional technical requirements for Bone Conduction Sound Processors are listed in Table 18, alongside the rationale for their inclusion in the minimum specifications.

Table 18: Technical Requirements for devices listed in Bone Conduction Sound Processor device categories

Category	Technical Requirements	Evidence/rationale
Acoustic output and adjustability	<ul style="list-style-type: none"> • The fitter must be able to adjust the stimulation levels with sufficient precision to enable the device to be programmed to meet the needs of the user • The fitter must be able to adjust the maximum stimulation level and over a range of adjustment wide enough that the device produces adequate loudness sensation while avoiding loudness discomfort 	<ul style="list-style-type: none"> • Bone conduction sound processors require sufficient controls to allow a clinician to fit the device to achieve good sensitivity to low sound levels while maintaining comfortable stimulation levels
Gain and compression	<ul style="list-style-type: none"> • The device must be capable of dynamically adjusting the gain it applies to incoming sounds to mitigate loudness discomfort 	<ul style="list-style-type: none"> • Automatic control over stimulation levels is essential to avoid discomfort

Category	Technical Requirements	Evidence/rationale
Backwards compatibility	<ul style="list-style-type: none"> BCSPs must be backward compatible with the same attachment type from the same manufacturer that have been on the market in Australia in the 10 years prior to the device being submitted for listing on the Device Schedule 	<ul style="list-style-type: none"> The long lifespan of the implantable component of implantable bone conduction and middle ear systems means backwards compatibility is essential for sound processors
Internal microphone diagnostics	<ul style="list-style-type: none"> BCSPs must enable clinicians and users to monitor both the functionality (e.g. microphone listening check or visual alerts) and sound quality (e.g. microphone listening check/self-diagnostics) of the internal microphone(s) 	<ul style="list-style-type: none"> Unlike hearing aids, whose functionality can be checked by listening to them, additional features are required to confirm the full functionality of the sound processor

Section 8: Discussion

The current report presents recommendations for the minimum specifications that all subsidised devices (whether fully- or partially-subsidised) under the Hearing Services Program should meet. The development of these minimum specifications was guided by four key principles:

- (1) The minimum specifications should reflect the features widely available in subsidised devices being provided on the Program at the present time;
- (2) The minimum specifications should ensure there is increased access to newer technologies for clients of the Program;
- (3) The minimum specifications should allow manufacturers to introduce new technologies or innovations that benefit the client without deterrents;
- (4) The minimum specifications should ensure there is continued access to core assistive technologies that remain important for certain subsets of Program clients.

By addressing these principles, the recommendations aim to strike a balance between promoting innovation, ensuring access to critical technologies, and meeting the diverse needs and preferences of Program clients.

Within the minimum specification, the technical requirements for devices listed under the Hearing Services Program have been refreshed to better align with advances in hearing device technologies and evolving consumer preferences and trends. Notably, modern hearing devices have undergone significant advancements in digital signal processing hardware and techniques over the years. As a result, many of the electroacoustic performance criteria outlined in the existing minimum specifications are now easily met by modern devices, and market forces will ensure that new products continue to satisfy most of these requirements.

The revised technical requirements, specified where necessary and appropriate, maintain adequate provisions for clinicians to fit devices to individual client needs and to ensure acceptable sound quality and user comfort. This includes technical criteria for dynamic gain control, harmonic distortion, and equivalent input noise. Moreover, the report identifies a need to include expanded technical requirements for both disposable and rechargeable batteries in hearing aids. These battery criteria were selected based on present-day capabilities of devices in addition to typical client needs and usage patterns, ensuring that the recommendations are both feasible for the industry to adhere to and aligned with client expectations as device users.

The recommendations include requirements for the inclusion of features that are widely prevalent in devices currently provided under the Program and that offer benefits substantiated by relevant literature. This includes features such as automatic and adaptive directional microphones, adaptive noise reduction, feedback prevention and soft noise reduction. Mandating these features is essential to ensure a baseline of acceptable performance, comfort and user experience across all devices subsidised under the Program. The recommendations also include minimum performance specifications for such features, where appropriate.

The report also recommends the inclusion of several newer hearing aid technologies in the minimum specification to align with consumer needs and preferences. Wireless streaming is already prevalent in currently supported devices and favoured by consumers (Picou, 2022), and thus recommended for inclusion. Consumers also prefer rechargeable devices, prompting the inclusion of requirements for manufacturers to provide rechargeable

options for hearing aids under the BTE/RIC category. This recommendation only relates to the internal battery and does not imply that a means of charging the battery should be provided free of charge with the device. The provision of a charging method is a separate consideration for the Program to make in light of the current recommendation to require manufacturers to list rechargeable devices. Despite their smaller form factor and high prevalence in overseas markets, few RIC hearing aids are currently subsidised under the Program. To address this, the recommendations include a requirement for manufacturers to list a RIC device if they wish to list hearing aids in any other category.

This report and the current recommendations have been developed with the awareness that this is a period of rapid technological progress, particularly in areas such as artificial intelligence. The minimum specifications have been formulated to acknowledge these emerging technologies and support innovation, ensuring that manufacturers are not restricted in innovating and bringing consumers the latest advancements in technology. However, it is also essential that the minimum specifications also ensure continuing access to certain features that some clients may still rely on. For instance, certain core assistive features like telecoil and manual controls remain crucial for some clients. The recommendations acknowledge this reality and aim to ensure continued access to these technologies in subsidised hearing aids provided under the Program.

Finally, to address the rapid pace of technological change, we recommend more frequent reviews and updates to the minimum specifications, ideally every 24 months. This regular review process will ensure that the minimum specifications remain relevant and align with the latest advancements in the field, while also accommodating shifting consumer preferences and market trends.

Section 9: References

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Appendix 1: Recommendations for the Minimum Specifications for Subsidised Devices

Section A1: Hearing device categories

All devices must be listed under one of the device categories listed in Table A1.

Table A1. Device categories

Device Category	Device Type
Hearing Aids (HA)	
HA BTE	Behind the ear (BTE)
HA RIC	Receiver in the canal (RIC)
HA C	Custom (C) ITE, ITC, CIC, or IIC
HA NC	Non custom (NC) ITE, ITC, CIC, or IIC
Assistive Listening Devices (ALD)	
ALD TM	TV/Music (TM) Hearing Systems
ALD PS	Personal Sound Amplifier (PS) (without TV/Music Hearing System feature)
ALD PS +TM	Personal Sound Amplifier (PS) (with TV/Music Hearing System feature)
ALD SFF	Supported Self-Fitting (SFF) hearing device
Contralateral Routing Of Signals (CROS)	
CROS	Unilateral and Bilateral Contralateral Routing Of Signals (CROS/BiCROS)
Cochlear Implant Sound Processors (CISP)	
CISP BTE	Behind the ear (BTE)
CISP OTE	Off the ear (OTE)
CISP BTE + EAS	Behind the ear (BTE) (with Electro-Acoustic System)
Bone Conduction Sound Processors (BCSP)	
BCSP IMT	Integrated mechanical transducer (such that can be worn on an abutment or headband)
BCSP NMT	Non-integrated mechanical transducer (requires surgical implant)

Devices listed in any device category for Hearing Aids (HA) may also be listed with one or more of the device supplements listed in Table A2.

Table A2. Device supplements

Device Supplement	Supplement qualifications
Hearing Aids (HA)	
HA +R	Battery is rechargeable (R)*
HA +HP	High powered (HP) device with OSPL90 ≥ 128SPL

**Note that this supplement only relates to the internal battery and does not imply that a means of charging the battery is to be provided free-of-charge with the device.*

Definitions for each category of Assistive Listening Devices (ALD) is provided in Table A3.

Table A3: Definitions of device categories

Device category	Technical definition
Hearing Aids (HA)	
Behind the ear (HA BTE)	An ear-worn hearing aid in which the sound is produced using a transducer located internal to the hearing aid itself and coupled to the ear canal using a tube
Receiver in the canal (HA RIC)	An ear-worn hearing aid in which the sound is produced using a transducer located inside the ear canal
Custom ITE, ITC, CIC, or IIC (HA C)	A hearing aid worn in the ear (partly or fully in the canal) whose shape is personalised to the wearer using a custom molded shell
Non custom (NC) ITE, ITC, CIC, or IIC (HA NC)	A hearing aid worn in the ear (partly or fully in the canal) which is coupled to the wearer's ear using various domes to fit a wide range of ear canals
Assistive Listening Devices (ALD)	
TV/Music Hearing Systems	An Assistive Listening Device which is explicitly designed to connect to a television or other audio source and transmit the sound to the user via earphones, headphones, telecoil, or another headset.
Personal Sound Amplifier	An Assistive Listening Device which is designed to provide the user basic amplification of acoustic sound via earphones, headphones, telecoil, or another headset. These devices are generally handheld or body worn and consist of an amplifier component that is separate from the ear-worn component.
Personal Sound Amplifier with TV/Music Hearing System Feature	A Personal Sound Amplifier ALD which includes an additional component, in the form of an audio transmitter, which allows for the additional function of a TV/Music Hearing System.
Supported Self-Fitting (SFF) Hearing Devices	A self-contained ear-worn device or set of devices which provide personalised acoustic amplification to the wearer by means of a self-fitting or hearing assessment feature, pre-defined sound profile, or limited choice of preset profiles.
Contralateral and Bi-Contralateral Routing of Signals (CROS/BiCROS)	

Contralateral and Bi-Contralateral Routing of Signals (CROS)	A device which is intended as part of its core functionality to re-route signals detected on the side of a poorer-hearing ear and reproduce those signals in a better-hearing ear, including devices that also provide amplification to address hearing loss in the better-hearing ear
Cochlear Implant Sound Processors (CISP)	
Behind the ear (CISP BTE)	An ear-worn device that communicates with or connects to the implantable component of a cochlear implant system. These devices attach magnetically to the receiver/stimulator package of the implantable component wherever it is located on the head.
Off the ear (CISP OTE)	A device that is designed to be worn off the ear that communicates with or connects to the implantable component of a cochlear implant system. This do not include BTE processors that can be adapted to be worn off the ear using accessories; such processors should be listed in the CISP BTE category.
Behind the ear (BTE) (with Electro-Acoustic System) (CISP BTE + EAS)	A behind-the-ear sound processors that is configured such that it is capable of delivering both electrical and acoustic stimulation (EAS) through one integrated device; that is, it can both fulfil the functionality of a cochlear implant sound processor and act as an acoustic hearing aid
Bone Conduction Sound Processors (BCSP)	
Integrated mechanical transducer (BCSP IMT)	A bone conduction device with an integrated mechanical transducer that converts electrical audio signals into mechanical vibrations, including devices that can be worn on an abutment or headband. These vibrations are then transmitted through the bones of the skull to the inner ear, bypassing the outer and middle ear.
Non-integrated mechanical transducer (BCSP NMT)	A sound processor that does not generate vibrations directly, but rather communicates with or connects to an implantable component that generates the vibrations required to achieve the bone conduction of sounds.

Section A2: Minimum Specifications for Hearing Aids

Feature requirements

All subsidised devices listed in device categories for Hearing Aids must include the features listed in Table A4. Certain features must also meet the minimum performance specifications listed in Table A5. Definitions for all features are provided in Section A6.

Table A4: Minimum specifications for features of devices listed in device categories for Hearing Aids

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)
Hearing Aids (HA)	
HA BTE and HA RIC	<ul style="list-style-type: none"> • Automatic directional microphone • Adaptive directional microphone* • Adaptive noise reduction* • Feedback prevention* • Soft noise reduction* • Ear-to-ear communication • Accessory connectivity • App connectivity • Remote clinician adjustments • Phone streaming • Data logging
HA C and HA NC (excluding CIC and IIC)	<ul style="list-style-type: none"> • Automatic directional microphone • Adaptive directional microphone* • Adaptive noise reduction* • Feedback prevention* • Soft noise reduction* • Ear-to-ear communication • Accessory connectivity • App connectivity • Remote clinician adjustments • Phone streaming • Data logging
HA C and HA NC (CIC and IIC only)	<ul style="list-style-type: none"> • Adaptive noise reduction* • Feedback prevention* • Soft noise reduction* • Data logging

* Feature must meet minimum performance specification listed in Table A5.

Table A5: Minimum performance specifications for Hearing Aid features

Feature	Minimum performance definition	Minimum performance requirement
Adaptive Directional microphone	Capable of achieving a minimum Articulation-Index-weighted Directivity Index (AI-DI)	<ul style="list-style-type: none"> • 3 dB for closed fittings or vents up to 2mm diameter • 2 dB for open fittings or vents >2mm diameter

Feature	Minimum performance definition	Minimum performance requirement
Adaptive noise reduction	Capable of achieving a minimum improvement in signal-to-noise ratio (SNR)	5 dB
Feedback prevention	Capable of achieving a minimum additional stable gain before feedback	10 dB
Soft noise reduction	Capable of achieving a minimum attenuation of noise at or below the levels of soft speech	3 dB

Client choice and access requirements

Note: these requirements are not affected by whether a device supplement (+R, +HP) is applied to a device.

Receiver in the canal (RIC) hearing aids

A Supplier who wishes to list a Hearing Aid (HA) device in any of the hearing aid device categories other than Receiver in the canal (RIC) must already have a device listed in the Receiver in the canal (RIC) hearing aid device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices).

Rechargeable hearing devices

A Supplier who wishes to list a Hearing Aid (HA) device in either the Behind the ear (BTE) or Receiver in the canal (RIC) categories must already have a device with a rechargeable battery listed in the same device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices). This recommendation only relates to the internal battery and does not extend to the provision of a battery charger.

Telecoil

A Supplier who wishes to list a Hearing Aid (HA) device in any of the hearing aid device categories must already have a device that incorporates an effective telecoil and means for enabling the telecoil in the same device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices). Where it is not possible for Supplier to list a device that incorporates an effective telecoil and means for enabling the telecoil, a Supplier must list a device in the same device category on the same device schedule that includes an accessory, free of charge, that accommodates this requirement.

Manual controls

A Supplier who wishes to list a Hearing Aid (HA) device in either the Behind the ear (BTE) or Receiver in the canal (RIC) categories must already have a device that incorporates a means to adjust the volume manually using a physical control on the device listed in the same device category on the same device schedule (i.e. the Main Schedule of Approved Devices or the Top-Up Schedule of Approved Devices).

Technical requirements

All subsidised devices listed in device categories for Hearing Aids must comply with the requirements detailed in Table A6.

Table A6: Technical Requirements for devices listed in Hearing Aid device categories

Category	Technical Requirements												
Acoustic output and adjustability	<ul style="list-style-type: none"> The fitter must be able to adjust the gain at a minimum of 5 frequencies (250, 500, 1000, 2000, and 4000 Hz) and at a minimum of 3 input sound pressure levels (at least one <55 dB SPL, at least one between 60-70 dB SPL, at least one >75 dB SPL) with sufficient precision to enable the device to be programmed to and verified against a prescriptive target. The fitter must be able to adjust the maximum output level (OSPL90) at a minimum of 5 frequencies (250, 500, 1000, 2000, and 4000 Hz) and over a range of adjustment wide enough that the device produces adequate loudness sensation while avoiding loudness discomfort. The device must have a minimum operating bandwidth of 200 Hz to 4000 Hz. 												
Gain and compression	<ul style="list-style-type: none"> The device must be capable of dynamically adjusting the gain it applies to incoming sounds to: <ul style="list-style-type: none"> match the intended output dynamic range at different frequencies as specified by a prescriptive target, mitigate loudness discomfort and distortion. 												
Distortion and noise	<ul style="list-style-type: none"> The harmonic distortion (HD)² must not exceed the following values: <ul style="list-style-type: none"> 7% at 500 Hz with 70 dB input SPL, 7% at 800 Hz with 70 dB input SPL, 3% at 1600 Hz with 65 dB input SPL. The Equivalent Input Noise (EIN)² must not exceed 31 dB SPL. 												
Durability and lifespan	<ul style="list-style-type: none"> The device must be capable of operating while being exposed to levels of moisture, temperature, humidity and dust that would be expected to arise from typical usage in the Australian climate. 												
Battery life	<ul style="list-style-type: none"> The supplier must provide estimations of battery life for typical use within publicly available data sheets, and estimates should indicate the proportion of time allocated to wireless streaming. For hearing aids with non-rechargeable batteries, the minimum battery life required under typical usage conditions (including a minimum of 25% wireless streaming) is: <table> <tr> <th>Battery type</th><th>Minimum battery life</th></tr> <tr> <td>Type 10</td><td>48 hours</td></tr> <tr> <td>Type 312</td><td>48 hours</td></tr> <tr> <td>Type 13</td><td>80 hours</td></tr> <tr> <td>Type 675</td><td>80 hours</td></tr> </table> <ul style="list-style-type: none"> For hearing aids with rechargeable batteries, the minimum specifications for battery life under typical usage conditions (including a minimum of 25% wireless streaming), charging time, and lifespan of the rechargeable battery are: <table> <tr> <td>Minimum battery life</td><td>16 hours per charge</td></tr> </table>	Battery type	Minimum battery life	Type 10	48 hours	Type 312	48 hours	Type 13	80 hours	Type 675	80 hours	Minimum battery life	16 hours per charge
Battery type	Minimum battery life												
Type 10	48 hours												
Type 312	48 hours												
Type 13	80 hours												
Type 675	80 hours												
Minimum battery life	16 hours per charge												

² As defined in IEC60118-0:2022 or ANSI/ASA S3.22-2014 (R2020)

Category	Technical Requirements
Maximum charging time	4 hours from fully discharged to fully charged
Minimum battery lifespan	80% of original runtime after 2 years of regular use, or 80% of battery capacity after 2 years of regular use

Section A3: Minimum Specifications for Assistive Listening Devices

Feature requirements

All subsidised devices listed in each device category for Assistive Listening Devices (ALD) must include the features listed in Table A7. Definitions for all features are provided in Section A6 of this report.

Table A7: Minimum specifications for features of devices listed in device categories for Assistive Listening Devices

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)
Assistive Listening Devices (ALD)	
ALD TM	<ul style="list-style-type: none"> • Rechargeability • Stereo/binaural sound delivery • Volume control
ALD PS	<ul style="list-style-type: none"> • Rechargeability • Stereo/binaural sound delivery • Volume control • Frequency shaping
ALD PS +TM	<ul style="list-style-type: none"> • Rechargeability • Stereo/binaural sound delivery • Volume control • Frequency shaping • Direct audio input • Accessory connectivity
ALD SFF	<ul style="list-style-type: none"> • Stereo/binaural sound delivery • Volume Control • Frequency shaping • Noise reduction • Directional microphones • Accessory connectivity • Phone Streaming • Custom programs • App connectivity • Self-fitting

Section A4: Minimum Specifications for Cochlear Implant Sound Processors

Feature requirements

All subsidised devices listed in device categories for Cochlear Implant Sound Processors must include the features listed in Table A8. Definitions for all features are provided in Section A6 of this report.

Table A8: Minimum specifications for features of devices listed in device categories for Cochlear Implant Sound Processors.

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)
Cochlear Implant Sound Processors (CISP)	
BTE and BTE + EAS	<ul style="list-style-type: none"> • Automatic directional microphones • Automatic environment-based adjustments • Adaptive directional microphones • Adaptive noise reduction • Soft noise reduction • Accessory Connectivity • App Connectivity • Rechargeability • Remote Clinician Adjustments • Phone Streaming • Data Logging
OTE	<ul style="list-style-type: none"> • Automatic directional microphones • Automatic environment-based adjustments • Adaptive directional microphones • Adaptive noise reduction • Soft noise reduction • Accessory Connectivity • App Connectivity • Rechargeability • Remote Clinician Adjustments • Phone Streaming • Data Logging

Technical requirements

All subsidised devices listed in device categories for Cochlear Implant Sound Processors must comply with the requirements detailed in Table A9.

Table A9: Technical Requirements for devices listed in Cochlear Implant Sound Processor device categories

Category	Technical Requirements
Acoustic output and adjustability	

Category	Technical Requirements
	<ul style="list-style-type: none"> The fitter must be able to adjust the stimulation levels with sufficient precision to enable the device to be programmed to meet the needs of the user The fitter must be able to adjust the maximum stimulation level and over a range of adjustment wide enough that the device produces adequate loudness sensation while avoiding loudness discomfort
Gain and compression	<ul style="list-style-type: none"> The device must be capable of dynamically adjusting the gain it applies to incoming sounds to mitigate loudness discomfort
Form factor	<ul style="list-style-type: none"> Off-the-ear (OTE) CISPs must be devices designed to have a form factor that is distinct from behind-the-ear (BTE) CISPs. OTE CISPs do not include BTE processors that can be adapted to be worn off the ear using accessories; such processors should be listed in the CISP BTE category
Directional microphones	<ul style="list-style-type: none"> CISPs must provide clinicians and users with the functionality to alter the behaviour of the microphone(s) so that they can be set to Fixed Directional mode (Maintains a consistent directivity pattern) and Omni Directional mode (Intended to capture sounds from all directions)
Backwards compatibility	<ul style="list-style-type: none"> CISPs must be backward compatible with all cochlear implants from the same manufacturer that have been on the market in Australia in the 10 years prior to the device being submitted for listing on the Device Schedule
Internal microphone diagnostics	<ul style="list-style-type: none"> CISPs must enable clinicians and users to monitor both the functionality (e.g. microphone listening check or visual alerts) and sound quality (e.g. microphone listening check/self-diagnostics) of the internal microphone(s)

Section A5: Minimum Specifications for bone conduction Bone Conduction Sound Processors

Feature requirements

All subsidised devices listed in device categories for Bone Conduction Sound Processors must include the features listed in Table A10. Definitions for all features are provided in Section A6 of this report.

Table A10: Minimum specifications for features of devices listed in device categories for Bone Conduction Sound Processors.

Device Category	Minimum specification (Device must include <u>all</u> of the features listed)
Sound Processor (BCSP)	
Bone conduction sound processors Integrated mechanical transducer (IMT)	<ul style="list-style-type: none"> • Automatic directional microphones • Automatic environment-based adjustments • Adaptive directional microphones • Adaptive noise reduction • Accessory Connectivity • App Connectivity • Phone Streaming • Data Logging • Feedback cancellation
Bone conduction sound processors Non-integrated mechanical transducer (NMT)	<ul style="list-style-type: none"> • Automatic directional microphones • Automatic environment-based adjustments • Adaptive directional microphones • Adaptive noise reduction • Accessory Connectivity • App Connectivity • Phone Streaming • Data Logging • Feedback cancellation

Technical requirements

All subsidised devices listed in device categories for Bone Conduction Sound Processors must comply with the requirements detailed in Table A11.

Table A11: Technical Requirements for devices listed in Bone Conduction Sound Processor device categories

Category	Technical Requirements
Acoustic output and adjustability	<ul style="list-style-type: none"> The fitter must be able to adjust the stimulation levels with sufficient precision to enable the device to be programmed to meet the needs of the user The fitter must be able to adjust the maximum stimulation level and over a range of adjustment wide enough that the device produces adequate loudness sensation while avoiding loudness discomfort
Gain and compression	<ul style="list-style-type: none"> The device must be capable of dynamically adjusting the gain it applies to incoming sounds to mitigate loudness discomfort
Backwards compatibility	<ul style="list-style-type: none"> BCSPs must be backward compatible with the same attachment type from the same manufacturer that have been on the market in Australia in the 10 years prior to the device being submitted for listing on the Device Schedule
Internal microphone diagnostics	<ul style="list-style-type: none"> BCSPs must enable clinicians and users to monitor both the functionality (e.g. microphone listening check or visual alerts) and sound quality (e.g. microphone listening check/self-diagnostics) of the internal microphone(s)

Section A6: Definitions of device features

Table A12: Definitions of features

Feature	Feature term definition
Accessory connectivity (wireless)	Links to other devices such as remote microphones for improved audibility in difficult listening environments, and other accessories that provide additional functionality beyond that of the hearing device alone.
Automatic directional microphone	Automatically switches between microphone directionality modes depending on the surrounding noise level.
Automatic environment-based adjustments	Automatic environment-based adjustments means that sound processors can make automatic adjustments to settings such as wearer's volume control settings and program preferences when a certain sound environment (for example, a noisy environment vs. a quiet one) is detected by an environmental classifier.
Adaptive directional microphone	Automatically varies microphone directivity pattern to adapt to spatially dynamic listening environments (E.g. Moving speech and/or noise sources).
Adaptive noise reduction	Automatically changes the gain-frequency response, either quickly or slowly, in a manner dependent on the variation of signal-to-noise ratio (SNR) across frequency, and that causes the overall SNR to increase.
App connectivity (wireless)	Connects to an app on a smartphone or tablet. At a minimum, this app must allow a user to remotely control the device settings (I.e. Volume and program changes).
Automatic directional microphone	Automatically switches between microphone directionality modes depending on the surrounding noise level.
Custom Programs	The ability for the user to set and choose a specific profile or sound quality to meet their preferences or needs; either through a guided process or through the user saving their preferences manually.
Data logging	Data logging enables the gathering and analysis of data from hearing devices, focusing on user behaviours, device performance, environmental conditions, and feature usage.
Direct Audio Input	A feature of an assistive listening device which allows the user to connect the device to an audio source via a wired connection.
Ear-to-ear synchronisation	Wireless communication that allows two hearing devices to work together as a synchronised system to control settings such as volume, programs, etc.
Feedback prevention	Reduces feedback oscillation (e.g. when the sounds hearing devices generate in the ear canal leak out of the ear canal back to the microphone), for example, by using the addition of a signal with identical gain and opposing phase response to cancel the feedback pathway.
Frequency Shaping	The ability for a device to provide varying levels of gain at different frequencies as determined by the manufacturer or set by the user.
Phone streaming (wireless)	Allows the wearer to wirelessly connect and stream audio and phone calls using their smartphone (E.g. via Bluetooth technologies such as Made for iPhone or Made for Android).
Noise reduction	Reduce the level of unwanted sounds. This can be achieved through a variety of different techniques, and includes Active Noise Cancellation (ANC) and Digital Signal Processing (DSP) techniques.
Rechargeability	Rechargeability refers to the use of battery technology such as lithium-ion instead of disposable batteries.

Feature	Feature term definition
Remote clinician adjustments	Allows an audiologist or other hearing care provider to fit or fine-tune hearing devices remotely via a smartphone app, computer or tablet.
Self-Fitting	A feature or set of features which enable a hearing device to ascertain the sound quality and amplification appropriate for the wearer; often via interpreting or conducting an in-situ hearing assessment.
Soft noise reduction	Uses expansion to reduce amplification of quiet noises that are not of interest (such as environmental noise or internal device noise) while preserving the amplification of sounds of interest.
Stereo/binaural sound delivery	Sound can be presented in two channels or into both ears.
Transient noise reduction	Reduces the discomfort of loud temporary noises. As sound is processed by the hearing device, any sudden loud noises are reduced, making them more comfortable to the wearer.
Volume Control	An ability for a user to manually adjust the loudness of the device to their personal preference.