ADVANCED BIONICS

POWERFUL CONNECTIONS

Naída CI Q90 Sound Processor

CI-5280

instructions for use
English

Contents

SYMBOLS TABLE

$C\epsilon$ 0123	European Community Mark of Conformity
REF	Model number
Date of manufacture symbol	Date of manufacture
SN	Serial Number
Manufacturer symbol	Manufacturer
Type of Protection: BF symbol	Type of Protection: BF
Temperature range symbol	Suitable temperature range for transport and storage
Fragile symbol	Fragile
Do not get wet symbol	Do not get wet

	See Instructions for Use
R	Refurbished*
	Dispose of in accordance with applicable national and local regulations
EC REP	European authorized representative
UDI	Unique Device Identifier
MD	Medical Device
IPxx	Ingress Protection Rating
	Caution (refer to "Precautions, Cautions and Warnings" section for further information)
	MR Unsafe

Only applicable if 'refurbished' is noted on the shipping label

PURPOSE AND SCOPE OF IFU

This IFU is designed to help cochlear implant recipients, and their caregivers if applicable, to understand the use and care of the Naída CI sound processors. It is also meant to be used by hearing care professionals trained in the fitting of cochlear implants to counsel the recipients on the use of the sound processors and to troubleshoot processor problems.

LIMITATIONS AND CONTRAINDICATIONS

As the Naída CI sound processors are a component of the HiResolution™ Bionic Ear System, the following contraindications stated for the HiResolution Bionic Ear System are applicable: deafness due to lesions of the acoustic nerve or central auditory pathway; cochlear ossification that prevents electrode insertion; absence of cochlear development; active external or middle ear infections; tympanic membrane perforations associated with recurrent middle ear infections.

⚠ PRECAUTIONS, CAUTIONS, AND WARNINGS

- *This device should be used only by the individual for whom it is prescribed.*
- *CHOKING HAZARD: contains small parts that pose a hazard of inhalation or choking.*

- *Do not use a ComPilot if recipient has a pacemaker, as there is potential for interference. Contact a healthcare professional for more information.*
- *Do not use or store the AB myPilot in shirt pockets if the recipient has a pacemaker, as there is potential for interference. Contact a healthcare professional for more information.*
- *Ensure appropriate supervision when child is wearing the Naída CI sound processor and accessories.*
- *Keep batteries and accessories out of children's reach as they may pose a choking hazard.*
- *If any parts are swallowed consult a physician or hospital immediately.*
- *Do not allow children to play with or leave them unattended with batteries.*
- *Do not place batteries in your mouth.*
- *Do not chew or swallow batteries. If this occurs, seek immediate medical attention.*
- *Do not allow children to play with or operate the drying system unattended.*
- *Using your sound processor and accessories contradictory to their intended use (e.g. mouthing, chewing) may cause bodily harm*
- *Do not recharge disposable batteries.*

- *Do not allow leaking battery fluid to come into contact with skin, mouth, or eyes.*
- *Do not expose batteries to heat (e.g., do not store in direct sunlight or in a hot car).*
- *Do not dispose of batteries in fire.*
- *Do not allow children to charge batteries unattended.*
- *Do not use any other power supply with the sound processor, AB myPilot remote control or ComPilot unless it is supplied by Advanced Bionics or Phonak. If needed call Advanced Bionics for a power supply replacement.*
- *Do not use the AB myPilot or the ComPilot when they are plugged in to power sources such as wall outlets or other power sources that are USB compatible such as laptops.*
- *The ComPilot comes with a neck loop antenna; do not touch the neck loop connectors at the same time.*
- *Unplug the neck loop from the ComPilot before pairing your ComPilot to a Bluetooth device to avoid unexpected sounds.*
- *Do not attempt to pair your ComPilot while driving or operating heavy machinery.*
- *Do not stream music to your ComPilot while driving or operating heavy machinery.*

- *Use your ComPilot for hands-free phone use only where permitted by law and only when you will not be distracted from the safe operation of your motor vehicle.*
- *Power supplies and battery chargers should be operated in an open area to ensure adequate airflow. While no injury cases have resulted, components may become hot during normal use or a fault condition. If the device's temperature results in discomfort or pain when touched, disconnect the power source and contact your local Advanced Bionics representative.*
- *Remove your sound processor and headpiece before entering a room where an MRI scanner is located.*
- *Remove external equipment to stop stimulation if uncomfortable sounds are heard.*
- *Having the correct magnet strength is important so the recipient does not experience discomfort or retention issues. If an insufficient number of magnets is used in the headpiece, it may fall off more than is acceptable. If too many magnets are used in the headpiece, you may experience irritation or discomfort. Consult a clinician if there are any concerns regarding magnet strength. If deemed appropriate, an audiologist may insert additional magnets or remove magnets from the headpiece. Do not place additional magnets in the headpiece unless under the direction of a cochlear implant professional. If the recipient experiences any redness, irritation, or discomfort, discontinue use*

of the headpiece immediately and contact a cochlear implant center. See the headpiece "Instructions for Use" for additional information regarding adjustment of headpiece magnet strength.

- If the sound processor or accessories become unusually hot, or warm, discontinue use immediately and contact Advanced Bionics or a clinician.
- Store additional headpieces away from items with magnetic strips (e.g. credit cards, hotel room key cards), as this may de-magnetize cards.
- Portable and mobile RF communications equipment, including radios and cellular phones, may affect sound quality of the Naída CI sound processor and accessories; however, there is no safety hazard associated with such equipment.
- The Naída CI sound processor and accessories should be used in accordance with the electromagnetic compatibility (EMC) information provided in the 'Guidance and Manufacturer's Declaration' section of this Instructions for Use.
- Only use the charger provided for charging AB PowerCel™ batteries. DO NOT use it to charge other batteries. Do not try to charge PowerCels* using a charger other than the one provided by Advanced Bionics.
- Remove batteries from your sound processor when they are drained to prevent damage from possible leaking.

* PowerCels refer to both PowerCels and PowerCel Minis unless otherwise noted

- *Do not expose any part of the Naída CI sound processor or accessories to extreme heat, such as an oven, microwave or hair dryer.*
- *Do not use your AB myPilot or ComPilot accessories when instructed not to use wireless electronic devices, such as on airplanes.*
- *The AB myPilot should not come within 1 cm (1/2") of the Naída CI processor while stimulating the implant, as doing so could cause the implant and sound processor to lose lock. If this happens, power down the processor and re-power on (done by disengaging the battery and reattaching).*
- *If the AB myPilot stops being able to transmit commands to the sound processor, it may be necessary to re-pair the AB myPilot with your sound processor. Consult the previous section of this user manual for instructions on re-pairing the AB myPilot.*
- *If volume commands from your AB myPilot to your sound processor seem erratic, re-pair the AB myPilot and the Naída CI.*
- *StereoZoom, auto UltraZoom and UltraZoom will dampen sounds that are not in front of the recipient.*
- *Do not use StereoZoom, auto UltraZoom or UltraZoom in an off-the-ear wearing configuration.*

- *Use of WindBlock, EchoBlock and/or SoundRelax may affect the quality of sound.*
- *However, when operating the device near a computer terminal or other strong electromagnetic fields (e.g., RFID system), it may be necessary to be at least 24" (60 cm) away to ensure proper operation. If the Naída CI does not respond to the implant device because of an unusual field disturbance, move away from the disturbing field.*
- *If the patient and/or caregiver is concerned about underlying skin conditions, have the attending physicians contact a dermatologists and/or rheumatologists.*
- *For Pediatric or immobile patients, if there is any question of discomfort or changes to skin in the area of implant or at the location of the external devices, the caregiver must be bring it to the attention of the attending physician.*

UNDESIRABLE SIDE EFFECTS

Undesirable side effects of the Naída CI system may include skin irritation and discomfort from pressure on the ear, device overheating, or overly loud sounds. If any undesirable side effect is encountered, please remove your sound processor and consult your cochlear implant professional.

PRODUCT DESCRIPTION AND PERFORMANCE CHARACTERISTICS

The Naída CI Q90 sound processor is a behind-the-ear (BTE) sound processor that converts sound picked up by the microphone into electrical signals that are used by the cochlear implant to enable hearing. The Naída Q90 sound processor is comprised of the components pictured below. The Naída Q90 offers multiple power options and wearing options for the user. The system is designed to provide useful hearing to individuals with severe-to-profound hearing loss.

Volume Control

Microphone ports

Light Emitting Diode
(LED)

Program
Button

Headpiece cable
connector

Battery connector
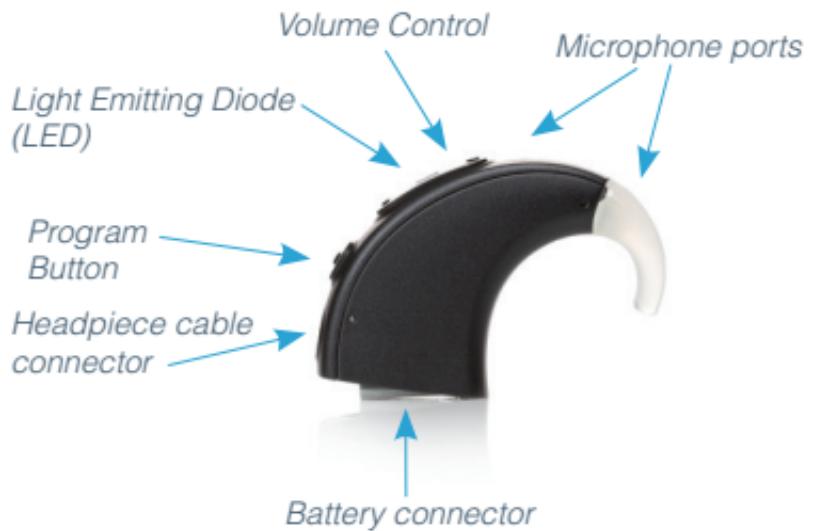
INDICATIONS FOR USE

The Naída CI sound processors are an external component of the HiResolution Bionic Ear System, which is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss via electrical stimulation of the auditory nerve.

Adults

- *18 years of age or older.*

- *Severe-to-profound bilateral sensorineural hearing loss or severe-to-profound unilateral hearing loss.*

- *Post-lingual onset of severe or profound hearing loss.*

- *Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences).*

Children

- *12 months through 17 years of age.*

- *Severe-to-profound bilateral sensorineural deafness or severe-to-profound unilateral hearing loss.*

- *Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea.*

- *Little or no benefit from appropriately fitted hearing aids. In younger children (< 4 years of age), lack of benefit is defined as a failure to reach developmentally appropriate auditory milestones (such as spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or ≤ 20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL). In older children (≥ 4 years of age), lack of hearing aid benefit is defined as scoring ≤12% on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or ≤ 30% on an open-set sentence test (Hearing In Noise Test for Children) administered using recorded materials in the sound field (70 dB SPL).*

INTENDED PURPOSE

The Naída CI sound processors are an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The Naída CI sound processors are behind the ear (BTE) sound processors which work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing. The Naída CI sound processors can be used by both adults and children, and provides dedicated pediatric hearing solution (multiple color options, and adjustable program for individual pediatric users). The Naída CI sound processors provide full access to multiple automatic programs and features including bimodal and bilateral and support compatibility with acoustic amplification.

Intended Users

The intended users of the Naida CI sound processors are recipients of Advanced Bionics cochlear implants, their caregivers if applicable, and hearing care professionals. The recipient, or their caregiver, should, at a minimum, be capable of changing the battery, connecting the earhook, 15 placing and removing the sound processor from their ear, and placing and removing the headpiece from the implant site. The hearing care professional should be trained in the use and fitting of the cochlear implant system.

Intended Use Environment

The Naida Q sound processor system is intended for use in healthcare and home environments. The home environment is extended to include use outdoors and during travel (e.g., airplanes). The Naida Q sound processor system is intended to operate with the SoundWave fitting software, and with Phonak RemoteMic, DECT Phone, Roger, TVLink II, MyPilot control devices or ComPilot devices used for audio streaming. The user is responsible for security of connections with other devices, including pairing the sound processor with other devices in a secure environment.

COMPATIBILITY

The Naída CI sound processors are compatible with the following implant types from Advanced Bionics:

- CII
- HiRes™ 90K
- HiRes™ 90K Advantage
- HiRes™ Ultra
- HiRes™ Ultra 3D

The Naída CI sound processors are compatible with the following Advanced Bionics products:

- PowerCel Batteries, Zn-Air Battery Pak, AquaCase™
- T-Mic™ 2 microphone, Naída CI Earhook, Acoustic Earhook

The Naída CI Q90 is compatible with the following programming interfaces:

- Advanced Bionics Clinical Programming Interface CPI-3 with the Programming Cable

The Naída CI Q90 is compatible with the following non-medical accessory products:

- Phonak Roger systems
- AB MyPilot
- Naída CI Connect
- Phonak Naída™ Link hearing instrument

Approved Naída CI Power Supplies

Power Supply	Rated Voltage	Type	Rated Energy/Power
PowerCel	3.7V	Li-ion (Rechargeable)	0.4 Wh-0.9 Wh
Zn-Air	2.8V	Zn-Air (Disposable)	1,240mWh
Programming Interface	5.0V	DC	1,250mW

OPERATING INSTRUCTIONS

Powering the Naída CI Q90

The processor is turned 'on' when a charged battery is attached to the processor. In order to power 'off' the processor, the battery cartridge must be removed. When the battery is engaged, the orange LED located in the middle of the rocker switch will flash to indicate battery charge.

The Naída CI Q90 will always power on in Program 1 with the volume and sensitivity at the default settings.

To power down the Naída CI, simply remove the battery cartridge.

NOTE: The T-Mic 2 Cover should be replaced at regular intervals to maintain sound quality.

Removing the Battery
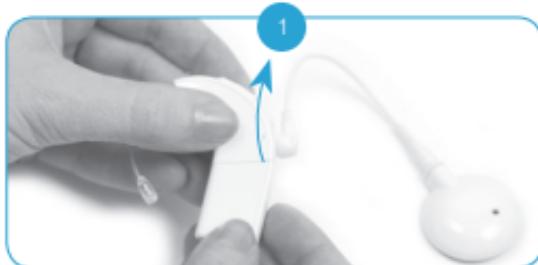
Hold the Naída CI in one hand. In the other hand hold the battery cartridge. Rotate RF cable upward in order to avoid bumping it upon battery removal.
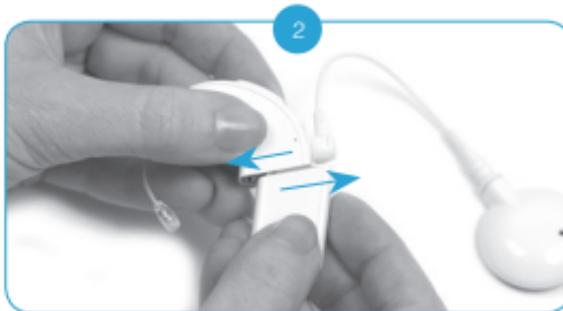
Firmly slide the battery cartridge away from the earhook or T-Mic 2.
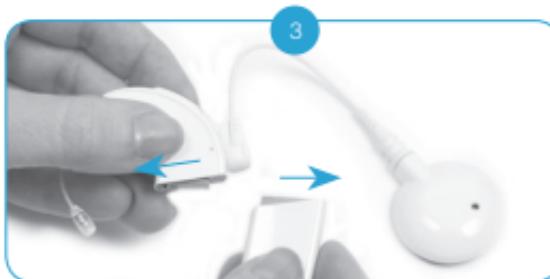
Continue sliding the battery cartridge until it separates from the processor.

Attaching the Battery
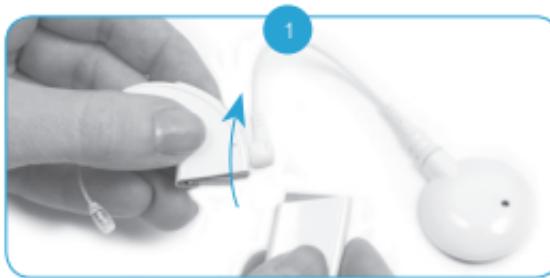
Hold the Naída CI in one hand. Rotate RF cable upward in order to avoid bumping it upon battery placement
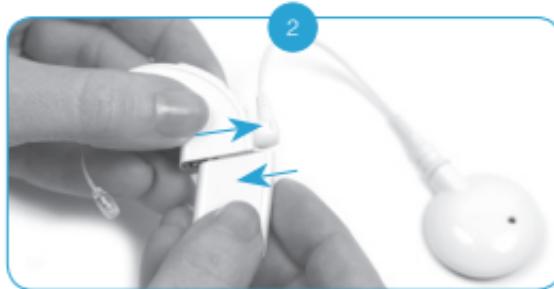
Align the battery cartridge connector with the processor housing side of the connector.
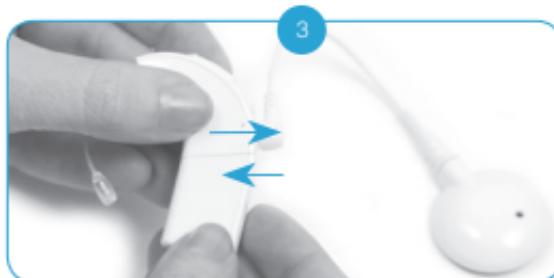
Slide the battery onto the processor until it clicks into place.

NOTE: Do not force the battery cartridge onto the processor. The battery cartridges are designed to be inserted in only one direction; applying force may damage the equipment.

Understanding Naída CI LEDs

The LED is a programmable feature providing visual information about Naída CI status, battery life, program position, and sound processor error conditions.

Color	Behavior	Programmable	Indication
Orange	Blinks at start-up	Battery indicator is only available with use of the rechargeable PowerCels and the Naída CI Power Adapter. *Battery life indicators are not available with Zn-Air cells.*	• 4 quick blinks indicate that the battery is fully charged • 2 - 3 quick blinks indicate that the battery is sufficiently charged to power the Naída CI • 1 quick blink indicates that the battery is nearly depleted • No blinking indicates depleted battery. Replace with charged or new battery
	Solid	Yes	The battery is almost depleted
Orange	Blinks twice every three seconds	Yes	The battery is depleted and cannot support stimulation (Sleep Mode)
	Fades out	No	Naída CI entering Standby Mode

Color	Behavior	Programmable	Indication
Red	Blinks once per second	Yes	Loss of lock with the implant
	Blinks rapidly (more than once per second)	No	IntelliLink™ safety feature: Wrong implant connected
	Solid	No	Sound processor error condition. Fully remove and re-insert battery to reset processor
	Blinks 5 times	No - if using AB myPilot, this pattern is the default	Response to AB myPilot's request to 'Find Paired Devices'. The *right* paired device will identify itself with this LED pattern

Color	Behavior	Programmable	Indication
Green	Flickers in response to loud inputs	Yes	The sound processor and microphone are responding to sound
	Blinks at start-up after battery status and upon program change	No	• 1 blink indicates program one • 2 blinks indicate program two • 3 blinks indicate program three • 4 blinks indicate program four • 5 blinks indicate program five
	Solid	No	A processor that is not yet programmed.
	Blinks 4 times	No - if using AB myPilot, this pattern is the default	Response to AB myPilot's request to 'Find Paired Devices'. The *left* paired device will identify itself with this LED pattern

NOTE: Use of some Naída CI accessories may obscure the processor LED.

If the user would like to know the battery status of the Zn-Air cells they are currently using and have an AB myPilot paired to their device, they can conduct a Battery Check readout of the Naída CI.

The Battery Check readout must be performed 15 minutes after the Zn-Air cartridge has been attached to the Naída CI. After this short window of time the AB myPilot will be able to give an accurate reading of the Zn-Air cells in use by the Naída CI.

Please see the 'Battery Check' section of the AB myPilot User Guide for instructions on how to conduct battery status check using AB myPilot.

The internal alarms are programmable and provide auditory information about the Naída CI Q90 sound processor. Your cochlear implant professional can adjust the volume and pitch of the internal alarms to suit your preference.

Understanding Naída CI Internal Alarms

Behavior	Programmable	Indication
Beeps upon program change	Yes	• 1 beep indicates program one • 2 beeps indicate program two • 3 beeps indicate program three • 4 beeps indicate program four • 5 beeps indicate program five
Short Beep upon increase/decrease in volume	Yes	Beeps once per press of the rocker switch either up or down (a double beep will be heard when the following settings are reached: top of the volume range; baseline volume setting; and bottom of the volume range)
Long Beep (once every 15 minutes)	Yes	Low battery

CARE AND MAINTENANCE

Storing the Naída CI sound processors

When not in use, store the Naída CI sound processor in the equipment case provided.

Recommended Operating and Storage Temperature Ranges

Condition	Minimum	Maximum
Operating Temperature	0˚C (32˚F)	47˚C (115˚F)
Storage Temperature	-20˚C (-4˚F)	55˚C (131˚F)

Cleaning & Maintenance

- Clean with a soft cloth. Do not immerse.

- Do not attempt to service or modify the Naída CI or its accessories. Doing so may compromise system performance and will void the manufacturer's warranty. Products should be serviced only at Advanced Bionics.

Expected Life

The expected life of the Naída CI sound processors is 5 years.

Ingress Protection (IP) Rating

The following product configuration has an IP rating of 52 (protection against dust; protection against failure due to dripping water when tilted up to 15°):

• The Naída Q90 Sound Processor inside the Aquacase with a compatible PowerCel Battery, RF cable with an IP52 rated headpiece.

The following product configurations have an IP rating of 54 (protection against dust; protection against failure due to water splashes from all directions):

• The Naída Q90 Sound Processor with a PowerCel battery or Zn-Air Battery Pak, a T-Mic or Acoustic Earhook or Earhook, RF cable and an IP54 rated headpiece.

The following product configuration has an IP rating of 57 (protection against dust; protection against failure due to one-time immersion for 30 minutes to a depth up to 1 meter and after drying overnight in a drying system):

• The Naída Q90 Sound Processor with a PowerCel Battery, an Earhook, RF Cable and an IP57 rated headpiece.

The following product configuration has an IP rating of 68 (complete protection against dust penetration; protection against failure due to continuous immersion in water up to 3 meters):

- The Naída Q90 Sound Processor in the Aquacase with a compatible PowerCel battery, RF cable and an IP68 rated headpiece.

DISPOSAL AND HAZARDOUS MATERIALS

Dispose of the Naída CI sound processors and accessories in accordance with applicable national and local regulations. Hazardous materials: not applicable to this product.

AVAILABLE PRODUCT OPTIONS AND MODEL NUMBERS

Description	Model Number
Naída CI Q90 Sound Processor[*†]	CI-5280-120, CI-5280-130, CI-5280-140, CI-5280-150, CI-5280-160, CI-5280-170, CI-5280-190, CI-5280-110, CI-5280-220, CI-5280-230, CI-5280-240

Description	Model Number
AquaMic*	CI-5306
PowerCel 110*	CI-5511-110, CI-5511-120, CI-5511-130, CI-5511-140, CI-5511-150, CI-5511-160, CI-5511-170, CI-5511-190, CI-5511-220
PowerCel 110 Mini*†	CI-5521-240
AquaMic Cable*	CI-5414-201, CI-5414-202, CI-5414-203, CI-5414-204, CI-5414-205, CI-5414-206, CI-5414-301, CI-5414-302, CI-5414-303, CI-5414-304, CI-5414-305, CI-5414-306, CI-5414-401, CI-5414-402, CI-5414-403, CI-5414-404, CI-5414-405, CI-5414-406, CI-5414-501, CI-5414-502, CI-5414-503, CI-5414-504, CI-5414-505, CI-5414-506
Universal Headpiece 2 (UHP2)	CI-5315
Concave UHP*	CI-5307

Description	Model Number
PowerCel Charger	CI-5605
PowerCel 170*	CI-5517-110, CI-5517-120, CI-5517-130, CI-5517-140, CI-5517-150, CI-5517-160, CI-5517-170, CI-5517-190, CI-5517-220
PowerCel 230*	CI-5523-110, CI-5523-120, CI-5523-130, CI-5523-140, CI-5523-150, CI-5523-160, CI-5523-170, CI-5523-190, CI-5523-220
PowerCel 170 Mini*	CI-5527-120, CI-5527-130, CI-5527-140, CI-5527-150, CI-5527-160, CI-5527-170, CI-5527-190, CI-5527-110, CI-5527-220, CI-5527-230, CI-5527-240
Zn-Air Battery Pak*	CI-5500-110, CI-5500-120, CI-5500-130, CI-5500-140, CI-5500-150, CI-5500-160, CI-5500-170, CI-5500-190, CI-5500-220, CI-5500-240, CI-5500-230

Description	Model Number
RF Cable*	CI-5415-301, CI-5415-302, CI-5415-303, CI-5415-304, CI-5415-305, CI-5415-201, CI-5415-202, CI-5415-203, CI-5415-204, CI-5415-205, CI-5415-401, CI-5415-402, CI-5415-403, CI-5415-404, CI-5415-405, CI-5415-501, CI-5415-502, CI-5415-503, CI-5415-504, CI-5415-505
T-Mic 2 Microphone*	CI-5835-100, CI-5835-200, CI-5835-300
Earhook*	CI-5710-100, CI-5710-200
Acoustic Earhook*†	CI-5850-001, CI-5850-002, CI-5850-003, CI-5850-004, CI-5850-005, CI-5850-006, CI-5850-007, CI-5850-008, CI-5850-009, CI-5850-010

*Applied part per IEC 60601-1

†Only available in markets where regulatory approval has been received and the product has been made commercially available. Contact Advanced Bionics for more information.

NOTE: model number extensions denote variants related to product color, size, and/or length.

Compatibility Tables

Implant Type						
Software Type/Version		C1	CII	HiRes 90K	HiRes 90K Advantage	Ultra	Ultra 3D
	SCLIN2000	✓	✓	-	-	-	-
	SoundWave 2.0	✓	✓	✓	✓	✓	✓
	SoundWave 3.1	✓	✓	✓	✓	✓	✓
	SoundWave 3.2	✓	✓	✓	✓	✓	✓

		C1	CII	HiRes 90K	HiRes 90K Advantage	Ultra	Ultra 3D
Programming Interface	CPI-3	-	✓	✓	✓	✓	✓

CLINICAL BENEFITS

The intended Clinical Benefits of the Naida CI Q90 sound processor as part of the HiResolution Bionic Ear System is to:

- provide useful hearing to individuals with severe-toprofound hearing loss via electrical stimulation of the auditory nerve.

- provide a combined type of stimulation, electric plus acoustic, when sound processors are enabled with the Acoustic Earhook.

Advanced Bionics has preformed two clinical studies -
"HiRes and HiRes 120 Sound Processing" and "ClearVoice"

Performance Data

The HiRes 90K™ Advantage implant with the HiFocus™ Electrode and Naída CI processor support the HiResolution family of sound processing strategies including HiRes, HiRes with Fidelity 120 (HiRes 120), and ClearVoice.

HiRes™ and HiRes 120™ Sound Processing

A clinical study was conducted in 50 adults implanted with a CII/HiRes 90K device who used a Harmony processor to document the benefits of HiRes 120 and

HiRes sound processing. Performance with HiRes was assessed at the baseline visit and compared with HiRes 120 performance after three months of listening experience. Subsequently, subjects were refit and retested with HiRes. Results showed equivalent mean CNC word recognition scores for the two strategies. The mean HINT sentence perception scores in quiet and noise were significantly higher for HiRes 120 compared to baseline with HiRes. For HINT sentences in noise, the mean scores for HiRes 120 were significantly higher than scores after subjects were refit with HiRes.

Table 1

Mean Speech Scores for HiRes and HiRes 120

Sound Processing Group	HiRes	HiRes 120	HiRes
Test Interval	Baseline	3 Months	3 Months
CNC Words	63	65	63
HINT Sentences in Quiet	88	93*	91
Hint Sentences in Noise (+8 dB SNR)	64	70**	65

* HiRes 120 score significantly different from baseline HiRes score (p<.05)
**HiRes 120 score significantly different from baseline and 3-month HiRes scores (p<.05)

Forty-three of 50 subjects (86%) preferred HiRes 120 over HiRes. Subjects rated strength of preference for the two strategies on a scale from 1 (weak preference) to 10 (strong preference). The mean strength of preference for the 43 subjects who preferred HiRes 120 was 7.9 (range: 1-10). The strength of preference was rated at 8 or higher by 26 of the 43 subjects, and 16 of the 43 subjects rated their preference as 10 (strong preference). For the 7 subjects who preferred HiRes, the mean strength of preference was 4.4 (range: 1-9).

ClearVoice™

A clinical study was conducted in 46 adults who had at least six months experience with HiRes 120 sound processing and at least moderate speech perception gain abilities to investigate the benefits of ClearVoice. ClearVoice has three adaptive gain settings that allow individuals to select the setting that provides the best hearing-Low, Medium, and High. A two-week randomized, crossover design was used to evaluate ClearVoice-Medium and ClearVoice-High. ClearVoice-Low was evaluated acutely during an initial test session. Speech benefit was compared for ClearVoice vs. HiRes 120 without ClearVoice (Control) using the AzBio sentence test.

Speech understanding in speech-spectrum noise was significantly better with ClearVoice-Medium and ClearVoice-High compared to the Control (p < .0001). ClearVoice-Medium significantly improved speech understanding in multi-talker babble (p< .02). Speech understanding was no worse than the Control when listening in quiet for both ClearVoice-Medium and ClearVoice-High (p < .0001). Speech understanding with ClearVoice-Low was no worse than the Control in quiet, in speech-spectrum noise, and in multi-talker babble (p <.001).

Table 2

Mean AzBio Sentence Scores for HiRes 120 with and without ClearVoice

Study Group	Control	Clear Voice Low	Control	Clear Voice Medium	Control	Clear Voice High
Quiet	87.3	87.8	88.6	88.3	86.8	87.7
Speech-Spectrum Noise	48.0	55.6	49.5	58.2	47.7	58.3
Multi-Talker Babble	42.8	47.2	44.9	48.1	44.9	46.2

Preference ratings indicated that 42 out of 45 subjects (93%) preferred ClearVoice to the Control for everyday listening (one subject did not complete the questionnaire). The mean strength of preference for the 42 subjects who preferred ClearVoice was 7.9 (1 = weak preference, 10 = strong preference). Of the 42 subjects preferring ClearVoice, 22 indicated they would use it all of the time, 17 indicated they would use it most of the time, and 3 indicated they would use it some of the time. Of the 3 subjects preferring the Control, all indicated they would use ClearVoice some of the time.

In the United States, ClearVoice is approved for pediatric use in children 6 years and above who are:
1) able to complete objective speech perception testing in order to determine speech performance; and
2) able to report a preference for different coding strategies or features ClearVoice is only available in markets where ClearVoice has received regulatory approval. Contact Advanced Bionics for more information.

Evaluation of Front-End Sound Processing Features of the Naída CI Sound Processor Family

Front-end sound-cleaning features (WindBlock, SoundRelax, EchoBlock) and beamforming options (auto UltraZoom, StereoZoom) are designed to improve

and/or ease listening ability in environmentally noisy and/or challenging listening environments for AB implant recipients using a Naída CI sound processor. A non-inferiority clinical study was conducted to demonstrate that there is no negative impact on speech understanding in quiet and noise when these features are enabled.

Subjects were 18 experienced adult recipients of CII/HiRes 90K implants (12 unilateral, 6 bilateral). Baseline AzBio sentence recognition was assessed acutely in quiet and in speech-spectrum noise. Then subjects were evaluated under the same conditions using each individual feature (WindBlock, SoundRelax, EchoBlock, auto UltraZoom) and a combination of features (WindBlock + SoundRelax + auto UltraZoom). StereoZoom was evaluated only in the bilaterally implanted subjects.

Subjects then experienced the features chronically over a four-week period. Using a randomized, blinded cross-over design, subjects were fit with either a single feature (auto UltraZoom) or a combined feature program (WindBlock + SoundRelax + auto UltraZoom), each for two weeks. Group A started with the single feature, and Group B started with the combined feature program. At the end of each two-week period, subjects completed a questionnaire that assessed their subjective comfort and acceptability of the feature(s).

In both the acute and chronic phases of the study, no software modifications to the subjects' listening programs were required for activation and successful use of the sound-cleaning and beamforming features.

Statistical analyses showed that sentence understanding in quiet and in speech-spectrum noise with the features enabled was no worse than in the baseline conditions (non-inferiority margin of 10; WindBlock, SoundRelax, EchoBlock, auto UltraZoom, combined SoundRelax+WindBlock+auto UltraZoom, noninferiority p-value < .0001; StereoZoom, non-inferiority p-value < 0.05). A critical difference score was used to determine whether individual subjects demonstrate a significant change in performance between the Baseline-Acute scores with his/her commercial owned sound processor and Naída CI Q90 sound processor. The value for the critical difference score is based upon the test-retest variance on the AzBio Sentence test. One subject (out of 18) had worse score difference between post-fitting and baseline testing for AzBio sentence test in noise with the combined features, however, the single or combined features were acceptable to this subject throughout the four-week trial period. Subjects who were dissatisfied with the new front-end processing features (single or combination) during the four-week trial period did not show worse AzBio sentence recognition scores with the new front-end-processing features turned on compared to off.

Table 3 shows the mean difference scores compared to baseline for each of the experimental front-end feature conditions.

Table 3

Mean AzBio Sentence Difference Scores (%) with front-end features enabled compared to baseline.

Test Condition	Quiet	Speech-Spectrum Noise
WindBlock alone	1.4	1.3
SoundRelax alone	2	0.2
EchoBlock alone	0.9	-2.2
auto UltraZoom alone	-0.2	2.7
WindBlock + SoundRelax + auto UltraZoom	1.4	2.3
StereoZoom alone*	0.4	8.5

*Bilaterally implanted subjects only

Questionnaires were administered during both the acute and chronic phases of the study to assess subjects' qualitative judgments of the sound-cleaning and beamforming features. At the time of acute testing, subjects were counseled with respect to the intended use of each feature (WindBlock, SoundRelax, EchoBlock, auto UltraZoom, and StereoZoom for bilateral subjects), evaluated, and then asked via a questionnaire whether each sound processing feature was acceptable (yes/no) and to rate the favorable aspects of each feature using a numeric scale from 1-7 (1=Strongly Disagree, 4=Neutral, and 7=Strongly Agree). Subjects used each feature in a simulated sound environment before completing the questionnaire.

During the chronic phase of the study, the same questionnaire format was used to evaluate subjective experience with auto UltraZoom alone and with a combined feature program (WindBlock + SoundRelax + auto UltraZoom). Responses were based upon subjects' use of the programs in their everyday listening environments. In the chronic phase, subjects were asked to assess both auto UltraZoom and the combined features after both two-week periods to maintain blinding of which programs were being activated during each period.

Acute questionnaires indicated that all individual features were acceptable by all subjects (18/18, 100%). Chronic questionnaires indicated that auto UltraZoom was acceptable by a majority of subjects (13/18, 72.2%) and that the combined

features (WindBlock + SoundRelax + auto UltraZoom) were acceptable by two thirds of the subjects (12/18, 66.7%).

Tables 4-8 list the median ratings for each feature from the questionnaires administered during both the acute and chronic phases of the study. Acute ratings were generally favorable for a majority of subjects with median values of 6 or 7 for all questions. The lowest acute response for any feature was a value of 3. Chronic ratings generally were a lower and more variable but most of the ratings had median values in the positive agreement range. This variability was an anticipated outcome given the randomized, cross-over blinded study design during the chronic phase. Tables 9-13 list the minimum, maximum, and median values for the two groups (A and B) on each subjective comfort question. Table 14 reports the overall acceptability rating for the combined feature program, Auto UltraZoom program, and EchoBlock for each group. Overall acceptability shows that there was no added benefit from the combined features compared to the auto UltraZoom alone (Table 14).

Table 4

Questionnaire results for WindBlock (median subjective ratings)

Item	Acute (WindBlock alone)	Chronic (in combined program)
WindBlock is acceptable in cancelling the wind noise	6.0	5.0
Hearing in wind is more comfortable with WindBlock	6.0	5.0
The WindBlock program is acceptable when listening in quiet	7.0	6.0

Table 5

Questionnaire results for SoundRelax (median subjective ratings)

Item	Acute (SoundRelax alone)	Chronic (in combined program)
SoundRelax is acceptable in quickly reducing unexpected abrupt sounds	6.5	4.5
Hearing loud sounds is more comfortable with SoundRelax	6.0	4.0
The SoundRelax program is acceptable when listening in quiet	7.0	5.0

Table 6

Questionnaire results for auto UltraZoom (median subjective ratings)

Item	Acute (auto UltraZoom alone)	Chronic (auto UltraZoom alone)	Chronic (in combined program)
Auto UltraZoom is acceptable in determining when to use the beamformer feature	7.0	5.0	3.5
The auto UltraZoom feature is acceptable when listening in quiet	7.0	6.0	5.5
The auto UltraZoom feature is acceptable when listening in noise	7.0	6.0	5.5

Table 7

Questionnaire results for EchoBlock (median subjective ratings)

Item	Acute (EchoBlock alone)	Chronic (EchoBlock alone)
EchoBlock is acceptable in cancelling echo sounds (reverberation)	7.0	5.0
Listening in an environment with reverberation is more comfortable using EchoBlock	7.0	5.0

Table 8

Questionnaire results for StereoZoom (median subjective ratings, bilateral subjects only)

Item	Acute (StereoZoom alone)
The StereoZoom program is acceptable when listening in noise	7.0
It is easier to hear in noise when using the StereoZoom program	7.0

Table 9

Questionnaire results for WindBlock (by Group)

Group A

Item	Group A		
	Min	Median	Max
WindBlock is acceptable in cancelling the wind noise	2	5	6
Hearing in wind is more comfortable with WindBlock	2	5	6
The WindBlock program is acceptable when listening in quiet	2	6	6

Group B

Item	Group B		
	Min	Median	Max
WindBlock is acceptable in cancelling the wind noise	2	6	7

Item	Group B		
	Min	Median	Max
Hearing in wind is more comfortable with WindBlock	2	6	7
The WindBlock program is acceptable when listening in quiet	1	7	7

Table 10

Questionnaire results for SoundRelax (by Group)

Group A

Item	Group A		
	Min	Median	Max
SoundRelax is acceptable in quickly reducing unexpected abrupt sounds	2	4	6
Hearing loud sounds is more comfortable with SoundRelax	3	4	6
The SoundRelax program is acceptable when listening in quiet	1	5	6

Group B

Item	Group B		
	Min	**Median**	**Max**
SoundRelax is acceptable in quickly reducing unexpected abrupt sounds	1	5	7
Hearing loud sounds is more comfortable with SoundRelax	1	6	7
The SoundRelax program is acceptable when listening in quiet	1	6	7

Table 11

Questionnaire results for Auto UltraZoom as part of combined program (by Group)

Group A

Item	Group A		
	Min	Median	Max
Auto UltraZoom is acceptable in determining when to use the beamformer feature	1	4	6
The auto UltraZoom feature is Acceptable when listening in quiet	2	5	7
The auto UltraZoom feature is acceptable when listening in noise	1	4	7
A program with auto Ultra-Zoom, WindBlock and SoundRelax is acceptable for daily use across a wide variety of environments	1	4	6

Group B

Item	Group B		
	Min	Median	Max
Auto UltraZoom is acceptable in determining when to use the beamformer feature	1	4	6
The auto UltraZoom feature is Acceptable when listening in quiet	1	6	7
The auto UltraZoom feature is acceptable when listening in noise	1	6	7
A program with auto Ultra-Zoom, WindBlock and SoundRelax is acceptable for daily use across a wide variety of environments	1	5	7

Table 12

Questionnaire results for Auto UltraZoom as stand-alone program (by Group)

Group A

Item	Group A		
	Min	**Median**	**Max**
Auto UltraZoom is acceptable in determining when to use the beamformer feature	2	4	7
The auto UltraZoom feature is Acceptable when listening in quiet	3	6	7
The auto UltraZoom feature is acceptable when listening in noise	2	6	7
A program with auto Ultra-Zoom, WindBlock and SoundRelax is acceptable for daily use across a wide variety of environments	2	4	7

Group B

Item	Group B		
	Min	Median	Max
Auto UltraZoom is acceptable in determining when to use the beamformer feature	1	6	7
The auto UltraZoom feature is Acceptable when listening in quiet	4	6	7
The auto UltraZoom feature is acceptable when listening in noise	5	6	7
A program with auto Ultra-Zoom, WindBlock and SoundRelax is acceptable for daily use across a wide variety of environments	2	6	7

Table 13

Questionnaire results for EchoBlock (by Group)

Group A

Item	Group A		
	Min	Median	Max
EchoBlock is acceptable in cancelling echo sounds (reverberation)	3	5	5
Listening in an environment with reverberation is more comfortable using EchoBlock	3	4	5

Group B

Item	Group B		
	Min	Median	Max
EchoBlock is acceptable in cancelling echo sounds (reverberation)	2	5.5	7
Listening in an environment with reverberation is more comfortable using EchoBlock	1	5.5	7

Table 14

Overall acceptability by Group

Group A

Item	Group A (N =8)	
	No	Yes
Is the combination of features, auto UltraZoom, WindBlock and SoundRelax acceptable	4 (50%)	4 (50%)
Is auto UltraZoom an acceptable feature	4 (50%)	4 (50%)
Is EchoBlock an acceptable feature	3 (37.5%)	5 (62.5%)

Group B

Item	Group B (N =8)	
	No	Yes
Is the combination of features, auto UltraZoom, WindBlock and SoundRelax acceptable	2 (20%)	8 (80%)
Is auto UltraZoom an acceptable feature	1 (10%)	9 (90%)
Is EchoBlock an acceptable feature	2 (20%)	8 (80%)

Only one adverse event was reported. One subject out of 18 (5.6%) experienced skin irritation from the external sound processor that was resolved. The adverse event was unrelated to the front-end features.

In summary, this clinical study demonstrated that use of the front-end sound-cleaning features (WindBlock, SoundRelax, EchoBlock) and beamforming options (auto UltraZoom, StereoZoom) in the Naída CI processor does not negatively affect speech understanding in quiet and in noise. Questionnaire results indicated that the features were acceptable, comfortable, and helpful to a majority of study participants. Modification of listening programs is not required in order to activate and use the features successfully.

COUNSELLING AND FITTING RECOMMENDATIONS

- **WindBlock:** The intent of the WindBlock sound processing feature is to reduce wind noise arriving at the microphone to improve comfort and ease listening when listening in the presence of wind. This is an automatic feature that can be enabled in an "everyday program".

- **SoundRelax:** The intent of the SoundRelax sound processing feature is to quickly respond to sudden and/or unexpected sounds. This is an automatic feature and can be enabled in an "everyday program".

- **EchoBlock:** The intent of the EchoBlock sound processing feature is to improve comfort and ease of listening when listening in environments with a high degree of reverberation or echo. This is not an automatic feature. A program with EchoBlock enabled is recommended for use only when in a highly reverberant environment (such as a gym court).

- **auto UltraZoom:** The intent of the auto UltraZoom sound processing feature is to improve the signal to enhance listening when focused on a person speaking in front of you. Auto UltraZoom activates in a noisy environment such as a restaurant when you are trying to listen to an individual speaker to you from the front. The feature will automatically enter or exit this mode depending on the surrounding noise in the environment and can be enabled in an "everyday program".

- **StereoZoom:** The StereoZoom feature is design only for use with bilateral recipients. The intent of this feature is to use a bilateral beamformer to create a narrow beam to focus on one person in front of you when in a noisy environment. This is not an automatic feature; therefore a program with StereoZoom enabled should only be used in a noisy environment when you want to dampen sounds to the sides and back.

Cautions

- UltraZoom is a beamforming algorithm; therefore, by design it focuses to the front and dampens sound from the side and back of the recipient.

- The Naída CI sound processor is designed so it can be worn in an off-ear wearing configuration. We do not recommend the processor be worn in the off-ear wearing configuration while using any beamforming algorithm.

- The intent of the WindBlock, EchoBlock, and SoundRelax algorithms is to attenuate a portion of the signal in order to provide comfort in specific environments. Attenuation of the signal may affect sound quality.

NOTE: In the United States, StereoZoom, auto UltraZoom, SoundRelax, WindBlock, and EchoBlock are approved for use in pediatric recipients 6 years and above who are:
1) able to complete objective speech perception testing in order to determine speech performance; and
2) able to report a preference for different coding strategies or features

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

A summary of safety and clinical performance (SSCP) is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI:- 08400944CI5280Y5 https://ec.europa.eu/tools/eudamed.

Users of the Naída CI sound processors in the European Union should report any serious incident to their local competent authority and to Advanced Bionics.

GUIDELINES FOR IT SECURITY

Intended Use Environment

The Naída CI Q sound processor system is intended to operate with the SoundWave fitting software, and with Phonak RemoteMic, DECT Phone, Roger™, TVLink II, MyPilot control devices or ComPilot devices used for audio streaming. The Naida CI Q90 sound processor can also connect to Bluetooth™ for streaming with other devices. The user is responsible for security of connections with other devices, including pairing the sound processor with other devices in a secure environment such as at home or in the clinician's office.

System and Network Diagram
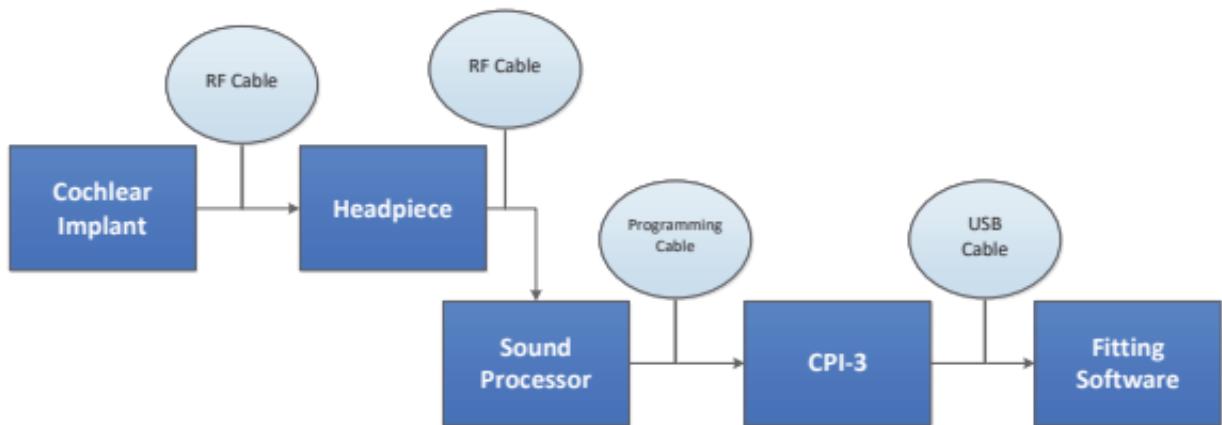
System Interfaces

Component	Sound Processor
Interface	RF
Data Transfer Direction	Bidirectional
Communication Protocol	Advanced Bionics proprietary
Security	None

Component	Roger Devices
Interface	Roger DMI
Data Transfer Direction	Bidirectional
Communication Protocol	Phonak proprietary
Security	32-bit code defining address and hopping sequence

Cybersecurity Configuration

There is no specific Naída CI Q sound processor configuration needed to help ensure cybersecurity. Ensure pairing with wireless devices is completed in a secure environment such as at home or in the clinician's office. Insecure pairing could allow another person to interfere with the normal operation of your sound processor.

Integrated Cybersecurity Functions

The Naída CI Q system does not include user authorization or authentication mechanisms. The sound processor is configured to connect with a single Advanced Bionics cochlear implant when fit with the SoundWave fitting software. All events are logged to an internal event log. Advanced Bionics can interpret and analyze the log if the device is returned. Data integrity and quality of service is ensured through sound processor and implant error correction and detection mechanisms.

System Configuration, and Data Backup/Restore

The user should discontinue use of the device and visit his or her cochlear implant professional if any unintended behavior of the sound processor is observed.

Warnings

Pair the sound processor to wireless devices only in a secure environment such as at home or in the hearing care professional's office.

Cybersecurity Incident Response

The Naída CI Q system does not detect cybersecurity attacks or intrusions. In case of abnormal behavior of the sound processor, please visit your cochlear implant professional or contact Advanced Bionics.

Patches and Updates

Advanced Bionics does not patch the Naída CI Q sound processor. Firmware updates may be made available from time to time and will require visiting your cochlear implant professional to reimage your sound processor. Authenticity of firmware can be verified by your cochlear implant professional using the SoundWave fitting software.

Available Training

Users of the Naída CI Q sound processor are trained by their cochlear implant professional at the initial fitting session.

End of Cybersecurity Support

Advanced Bionics products are supported until they no longer have regulatory approval in the country of use or until the product is obsoleted by Advanced Bionics.

HiBAN Wireless Link

Technical information

The sound processor uses a proprietary wireless technology, HiBAN, to enable communication between left and right processors (DuoPhone, QuickSync, and ZoomControl features) or a processor and AB myPilot or ComPilot accessories.

The HiBAN link operates in a 10.6 MHz band using a frequency shift keying (FSK) mechanism on a single channel.

The following table summarizes the technical details of the HiBAN technology implemented in the Naída CI sound processor platform:

	BTE	COMPILOT		AB MYPILOT
Antenna type	Integrated ferrite antenna	External neck loop antenna	Integrated ferrite antenna	Integrated ferrite antenna
Modulation	FSK	FSK		FSK
Output power (EIRP)	0.98nW	5.9nW	33nW	33nW
Range	≤18 cm to other BTE	≤30 cm	≤30 cm	≤60 cm to BTE, ≤30 cm readout from BTE
Center frequency	10.6 MHz	10.6 MHz		10.6 MHz
Bandwidth (99%)	596 KHz	588 KHz	570 KHz	512 KHz
Data rate	300 kBits/s	300 kBits/s		300 kBits/s

Quality of Service (QoS) for HiBAN

Wireless Link

HiBAN link enables communication between two processors and their paired accessories. A bit error rate better than $10-3$ is specified for all use cases at their nominal operating distance (See Table on previous page for the operating distances) for reliable audio and message transfer. For the remote control case, this QoS is further enhanced by redundant transmission of control messages. Each remote control command is transmitted 6 times, although only one successful transmission is needed for communication.

Wireless Security Measures

Security of the HiBAN link is ensured through the following measures:

1. A proprietary network protocol which creates and manage the devices in the network.
2. A unique pairing ID programmed to the processor and its accessories at fitting time which is validated during each transmission.
3. A cyclic redundancy check (CRC) which ensures the integrity of remote control data.
4. A system architecture that isolates the processor's critical functionality (patient-specific parameters) from HiBAN network.

GUIDANCE & MANUFACTURER'S DECLARATION
Per IEC 60601-1-2

Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Naída CI uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B, except at 49MHz and its harmonic frequencies	The Naída CI is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity

The Naída CI is intended for use in the electromagnetic environment specified below. The customer or the user of the Naída CI should assure that it is used in such an environment.

Immunity	IEC 60601 test level	Compliance level[a]	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. As with the operation of other electronic devices, precaution should be taken to not generate ESD.
Power frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Radiated RF IEC 61000-4-3	10 V/m from 80 MHz to 2.7 GHz	10 V/m from 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Naída CI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Proximity fields from RF Wireless Communications Equipment IEC 61000-4-3	9 V/m to 28 V/m from 385 MHz to 5.785 GHz	9 V/m to 28 V/m from 385 MHz to 5.785 GHz	**Recommended separation distance** $d = 1.2\sqrt{P} < 800$ MHz $d = 2.3\sqrt{P} \geq 800$ MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[b] should be less than the compliance level in each frequency range.[c] Interference may occur in the vicinity of equipment marked with the following symbol: $\left(\left(\left(\cdot\right)\right)\right)$

| Proximity Magnetic Fields IEC 31000-4-39 | 8 A/m @ 30 kHz, 65 A/m @ 134.2 kHz, 7.5 A/m @ 13.56 MHz | 8 A/m @ 30 kHz, 65 A/m @ 134.2 kHz, 7.5 A/m @ 13.56 MHz | Proximity magnetic fields should be at levels characteristic of a typical location in a typical home or professional healthcare environment |

Note 1: These guidelines may not apply in all situations.Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. There is no essential Performance of the Naída CI per IEC 60601 requirements.

b. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electro-magnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Naída CI is used exceeds the applicable RF compliance level above, the Naída CI should be observed to verify normal operation.

c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation distances between RF communications equipment and Naída CI

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Naída CI		
The Naída CI is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Naída CI can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Naída CI as recommended below, according to the maximum output power of the communications equipment.		
Rated Maximum Output Power of Transmitter (w)	Separation distance according to frequency of transmitter (m)	
	$d = 1.2\sqrt{P}$ < 800 MHz	$d = 2.3\sqrt{P}$ ≥ 800 MHz
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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