



Advanced Bionics AG
Laubisrütistrasse 28
8712 Stäfa, Switzerland
+41 58 928 78 00

Manufactured by:
Advanced Bionics LLC
California, U.S.A.
+1 661 362 1400

AdvancedBionics.com

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Naída CI












By Advanced Bionics

Naída CI Q70
CI-5245

instructions for use

English, French, Spanish, German, Dutch, Portuguese

Labeling symbols and their meanings:

	European Community Mark of Conformity. Authorized to affix the CE Mark in 20xx		
REF	Model number		Date of manufacture
SN	Serial Number		Manufacturer
	Type of Protection: B		Store at temperatures between -20°C (-4°F) and +55°C (131°F)
	Fragile		Do not get wet
LOT	Lot Number		See Instructions for Use
	Suitable for atmospheric range between 70kPa and 106kPa, which is equivalent to 3000m above sea level to 380m below sea level.		
	Suitable for exposure to relative humidity between 0-95%		
	Dispose of in accordance with applicable national and local regulations		
IP57	The Naída CI carries a rating of IP57. This rating indicates that the Naída CI is protected against the following conditions: <ul style="list-style-type: none"> • Protection against dust • Failure due to one time immersion for 30 minutes to a depth up to 1m and after drying overnight in a dry and store unit 		

Warnings and Cautions

Warnings

- **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 Naida 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 Zephyr by Dry & Store® or desiccant 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.
- 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.

Cautions

- Remove external equipment to stop stimulation if uncomfortable sounds are heard.
- It is important to have the correct magnet strength 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 Naida CI sound processor and accessories; however, there is no safety hazard associated with such equipment.
- The Naida 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 Naida CI 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.
- Do not expose any part of the Naida 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 Naida CI processor while stimulating the implant. 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).
- The digitally-coded, inductive transmission technology used in this device is extremely reliable and experiences virtually no interference from other devices. It should be noted, however, that when operating the device near a computer terminal or other strong electromagnetic fields, it may be necessary to be at least 60 cm (24") away to ensure proper operation. If the Naida CI does not respond to the implant device because of an unusual field disturbance, move away from the disturbing field.
- 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 Naida CI.
- Ultrazoom will dampen sounds that are not in front of the recipient.
- Do not use Ultrazoom in an off-the-ear wearing configuration.

The Naida CI 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.

Using the Naída CI Q70 Sound Processor

Powering the Naída CI

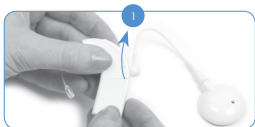
The processor is turned 'on' when a charged battery is attached to the processor. In order to power 'off' the processor, the battery cartridge must be removed. When the battery is engaged, the orange LED located in the middle of the rocker switch will flash to indicate battery charge.

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

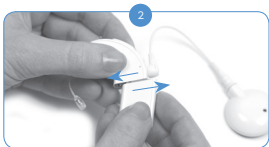
To power down the Naída CI, simply remove the battery cartridge.

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

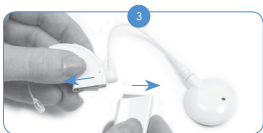
Removing the Battery



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.

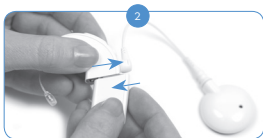


Continue sliding the battery cartridge until it separates from the processor.

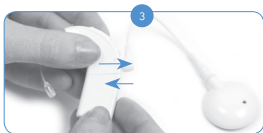
Replacing the Battery



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. <i>Battery life indicators are not available with Zn-Air cells.</i>	<ul style="list-style-type: none">• 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
	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™: 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	<ul style="list-style-type: none"> • 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 <i>left</i> 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.

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

Understanding Naída CI Internal Alarms

Behavior	Programmable	Indication
Beeps upon program change	Yes	<ul style="list-style-type: none">• 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

Recommended Operating and Storage Temperature Ranges

Condition	Minimum	Maximum
Operating Temperature	0°C (32°F)	45°C (115°F)
Storage Temperature	-20°C (-4°F)	55°C (131°F)

Naída CI External Equipment and Accessories

Model Number	Description
CI-5245-xxx	Naída CI Sound Processor*
CI-5305	Universal Headpiece (UHP)*
CI-5605	Naída CI PowerCel Charger
CI-5615	Charger Power Supply with adapters
CI-5415-xxx	Naída CI RF Cable*
CI-5511-xxx	Naída CI PowerCel 110*
CI-5517-xxx	Naída CI PowerCel 170*
CI-5523-xxx	Naída CI PowerCel 230*
CI-5500-xxx	Naída CI Zn-Air Battery Pak*
070-M006	Zn-Air Battery 6pk

*Applied part per IEC 60601-1

Note: The X's denote model number variant related to product color and/or length.

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	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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	3 A/m	3 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	3 V/m 80 MHz to 2.5 GHz 3	3 V/m	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. Recommended separation distance $d = 1.2\sqrt{P} < 800 \text{ MHz}$ $d = 2.3\sqrt{P} \geq 800 \text{ MHz}$ 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: 
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Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Essential performance of the Naida CI per IEC 60601 requirements is defined as auditory stimulation within safe amplitudes.

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 electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Naida CI is used exceeds the applicable RF compliance level above, the Naida 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	$d = 2.3\sqrt{P} \geq 800$ 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.

Compatibility Tables

		Implant Type			
Processor Type		C1	CII	HiRes 90K	HiRes 90K Advantage
	Naída CI	-	✓ ⁵	✓ ⁵	✓ ⁵
	Neptune	-	✓ ¹	✓ ¹	✓ ¹
	Harmony	✓ ²	✓ ³	✓ ³	✓ ¹
	Auria	-	✓ ³	✓ ³	✓ ¹
	Platinum Sound Processor (PSP)	✓ ⁴	✓	✓	✓ ¹

¹ Requires SoundWave 2.1 or later

² Requires SoundWave 2.0 or later

³ Requires SoundWave 1.4 or later

⁴ Requires SCLin2000 and CPI-II

⁵ Requires SoundWave 2.2 and CPI-3

Implant Type					
Software Type/Version		C1	CII	HiRes 90K	HiRes 90K Advantage
	SClin2000	✓	✓	-	-
	SoundWave (versions 1.x)	-	✓	✓	-
	SoundWave 2.0	✓ ¹	✓	✓	-
	SoundWave 2.1	✓ ¹	✓	✓	✓
	SoundWave 2.2	✓ ¹	✓	✓	✓

¹ Only on Harmony

Headpiece Type					
Processor Type		Universal Head-piece (UHP)	Aqua-Mic	Auria Head-piece	Platinum Head-piece (PHP)
	Naída CI	✓	✓	-	-
	Neptune	✓	✓	-	-
	Harmony	✓	-	✓	✓
	Auria	✓	-	✓	✓
	PSP	✓	-	-	✓

Programming Interface		C1	CII	HiRes 90K	HiRes 90K Advantage
	CPI-II	✓	✓	✓	✓
	CPI-3	✓ ¹	✓	✓	✓

¹ Only on Harmony

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.

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 as 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 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.

ClearVoice is not approved for pediatric use in the United States.

ClearVoice is only available in markets where ClearVoice has received regulatory approval. Contact Advanced Bionics for more information.

This instrument is certified under:



FCC ID: S2B-ABBTE
IC: 10870A-ABBTE

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Advanced Bionics may void the FCC authorization to operate this equipment.

This Class B digital apparatus complies with Canadian ICES-003.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult your clinic or an experienced radio/TV technician for help