



Warnings

Surgical processor and parts

- Your device contains magnets that should be kept away from life supporting devices (for example, cardiac pacemakers and ICDs (implantable cardioverter defibrillators) and magnetic ventricular shunts), as the magnets may affect the function of these devices. Keep your surgical processor at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- Your surgical processor and tablet radiate electromagnetic energy that may interfere with life supporting devices (for example, cardiac pacemakers and ICDs). Keep your surgical processor and tablet at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- Do not attempt stimulation of unsupported implants with Nucleus SmartNav or the surgical processor.
- Your surgical processor may be affected by other sound processors or coils. Always keep your surgical processor more than 1 cm away from other sound processors or coils.
- The surgical processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- Do not use excessive force on the surgical processor when in contact with the implant. Use of excessive force interferes with the surgical placement of the implant.
- Check the surgical processor for signs of overheating when in use. Remove the device immediately if it becomes hot.
- Do not expose the surgical processor or parts to heat.
- Do not use the surgical processor in a room where an MRI scanner is located.
- No modification of this equipment is allowed. Warranty will be void if modified.
- Consider security when connecting your surgical processor to devices. Only connect to devices that are protected, for example, password or PIN access control. Do not connect to devices that have had their operating system altered.



Batteries

- Do not use damaged or deformed batteries. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.
- Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep away from children.
- Do not short-circuit batteries (for example, do not let terminals of batteries contact each other, do not place batteries loose in pockets).
- Do not disassemble, deform, immerse in water or dispose of batteries in fire.
- When surgical processor is not in use, remove the batteries and store separately in a clean and dry place.
- Wipe batteries with a clean dry cloth if they become dirty.
- Store unused batteries in original packaging, in a clean and dry place.
- Do not expose batteries to heat.
- Never put batteries in your mouth. If swallowed, immediately contact your physician or local poison information service.
- Only use rechargeable batteries and battery chargers supplied by Cochlear. Use of other batteries or battery chargers may result in harm or injury.
- Charge rechargeable batteries before use.
- Do not touch the battery charger contacts.

Intraoperative considerations

When using the Cochlear Objective Measures software, the computer running the software must be positioned away from the operative field in a location that keeps cords from crossing the sterile field and out of the way of all operating room staff.





Medical treatments

Magnetic resonance imaging (MRI)



The Cochlear Surgical Processor is MR Unsafe. Do not use the surgical processor in the same room where an MRI scanner is located.

Full MRI safety information is available at:

www.cochlear.com/mri

or by calling your regional Cochlear office (contact numbers available at the end of this document).





Other information

Physical configuration

The processing unit comprises:

- custom analogue and digital integrated circuits with digital signal processing (DSP) and bidirectional wireless communication capabilities
- a tri-colour visual indication of surgical processor function or problem
- control button allowing user control of key features
- custom 4-pin connector for coil cable.

The batteries provide power to the processing unit. The coil acts as a transformer coupling that transfers energy and data to the implant.





Other information

Materials

The table below lists the materials of the main components of the CP1110S Surgical Processing Unit and Surgical Coils that come into contact with the skin.

Component	Material
Processing unit	Copolyester
Earhook	PA12 + liquid silicon rubber
Magnet	Neodymium
Magnet casing	ABS
Battery modules	Copolyester
Microphone cover	Copolyester
	GORE® cartridge: Oleophobic Polyester Blend Colour: White
Top housing	Copolyester
	Colour: Yellow
Bottom housing	Copolyester
	Colour: White
Coil	Polypropylene (PP)
	Thermoplastic elastomer (TPE)
Coil cable sheath	Polyvinyl chloride (PVC)
Coil spacer	Bormed RF830MO
Coil cable plugs	Polypropylene (PP) and
	Thermoplastic elastomer (TPE)

Battery life, charge cycles and lifespan

- Battery life means the time a device will run before the rechargeable battery module must be recharged.
- Battery charge cycle is a full charge and discharge of the rechargeable battery.
- Battery lifespan means the total number of charge cycles a rechargeable battery will last before the battery life degrades to 80% of its original fully-charged capacity.





Operating characteristics

Surgical processor and associated accessories

Factor	Conditions of use
Supplied sterile or non-sterile	Non-sterile
Special installation requirements	Not Applicable – device is not permanently installed
Equipment required for intended use	• Nucleus SmartNav or • Cochlear Research Platform Software and Cochlear Wired Programming Pod • Sterile covering
Mode of operation	Continuous operation

Environmental conditions

Condition	Minimum	Maximum
Storage and transport temperature	-10° C (+14° F)	+55° C (+131° F)
Storage and transport humidity	0% RH	90% RH
Operating temperature (surgical processor)	+5° C (+41° F)	+30° C (+86° F)
Operating temperature (battery charger)	0° C (+32° F)	+40° C (+104° F)
Operating relative humidity	0% RH	90% RH
Operating pressure	700 hPa	1060 hPa



Other information

Surgical processing unit

Characteristic	Value / range
Form factor	Behind the Ear (BTE)
Wireless data or power interfaces	• Proprietary radio-frequency (RF) link to implant • 2.4 GHz connectivity data link to compatible devices • Published commercial wireless protocol (Bluetooth Low Energy)
Wired data or power interfaces	Proprietary 6-pin (NEUF)
Magnets	Type: Imaging Strength: 5(I)
Battery options	Power Extend battery module
RF frequency	2.4 GHz
Max. RF output power	< 4 dBm
Input voltage	3.00 - 4.2 V (when using SmartNav only) 3.00 V (when using the Cochlear Wired Programming Pod only)
User interface	Button, Tri-colour LED indicator
Button functions	Turn surgical processor on and off, device verification
Colours	White, yellow (top housing), grey (button)



Battery module

Type	Capacity / voltage range
Power extend battery module	
Type and chemistry	Rechargeable lithium ion
Capacity / Nominal voltage	183 mAh / 3.7 V
Usable voltage range	3 – 4.2 V
Typical battery life (Battery autonomy)	At least 4 hours ¹
Battery recharge time	Less than 4 hours
Battery lifespan	>= 80 % capacity after 400 charge/discharge cycles at room temperature Values may vary depending on use
Colour options	White (same as processing unit and coil)

Coil

Characteristic	Value / range
Coil	Separate from processing unit (BTE), integrated cable
Variants	Surgical – includes in-line choke and in-line voltage booster 17 cm, 2 m lengths
Input voltage	2.6 V
Output voltage	3.3 V
Operating frequency	5 MHz
Transmission range	1 - 16 mm
Data rate	Variable – dependent on link mode
Colour options (coil and cable where applicable)	White (same as processing unit and battery module)

¹ Battery life (or Battery Autonomy) is based on two typical SmartNav sessions of one hour each and two hours of 'coil off time', with processor not paired with an implant, but still paired with the iPad running SmartNav





Other information

Product component dimensions (Typical values)

Length	Width	Depth	Diameter
Surgical processing unit with medium earhook and power extended battery module			
43.4 mm	8.9 mm	41.3 mm	N/A
Surgical Coil			
N/A	N/A	6.4 mm	30.7 mm
Power extend battery module			
24.8 mm	8.9 mm	17.6 mm	N/A

Product weight (Typical values)

Component			Weight
Surgical processing unit (no battery module)			3.3 g
Surgical processing unit with power extend battery module			9.4 g
Surgical coil and cable (without coil magnet)			8.5 g
Surgical coil (2 m) (without coil magnet)			19.2 g
	Type	Strength	Weight
Magnets	Imaging	5(I)	6.4 g



Wireless communication link

- Bluetooth Low Energy operates in the 2.4 GHz ISM band, using frequency hopping over 37 channels to combat interference. Operating range is up to 10 metres, and Nucleus SmartNav indicates when the surgical processor is out of operating distance (or switched off) or when the link is interrupted due to broad spectrum interference.

Equipment classification

Your sound processor is internally powered equipment Type B applied part as described in the international standard IEC 60601-1:2005/A1:2012+A2:2020, Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance.





Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration - electromagnetic emissions

The CP1110S Surgical Processor is intended for use in the electromagnetic environment specified below. The customer or the user of the CP1110S Surgical Processor should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The CP1110S Surgical Processor uses RF energy only for its internal function. RF emissions adhere to the requirements of the standards for use in the professional healthcare environment.
	Class A	The device is suitable for use in clinics and hospitals.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	



Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.



Guidance and manufacturer's declaration - electromagnetic immunity

The CP1110S Surgical Processor is intended for use in the electromagnetic environment specified below. The customer or the user of the CP1110S Surgical Processor should assure that it is used in such an environment.

Immunity Test	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge: ± 8 kV Air discharge: ± 2 , ± 4 , ± 8 , ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields 9 kHz to 13.56 MHz	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	Refer to <i>Guidance</i> on page 49.



Other information

Guidance and manufacturer's declaration - electromagnetic immunity

The CP1110S Surgical Processor is intended for use in the electromagnetic environment specified below. The customer or the user of the CP1110S Surgical Processor should assure that it is used in such an environment.

Electromagnetic environment - guidance

Portable and mobile RF communications equipment should be used no closer to any part of the CP1110S Surgical Processor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity Test: Conducted RF IEC 61000-4-6

Compliance Level: 3 V 0.15 to 80 MHz; 6 V in ISM 0.15 to 80 MHz

Recommended separation distance $d = 1.16\sqrt{P}$

Immunity Test: Radiated RF IEC 61000-4-3

Compliance Level: 3 V/m 80 MHz to 2.7 GHz

$d = 0.35\sqrt{P}$ 80MHz to 800MHz

$d = 0.70\sqrt{P}$ 800 MHz to 2.7 GHz

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, should be less than the compliance level in each frequency range.

Immunity Test: Proximity fields from RF wireless communications equipment IEC 61000-4-3. Refer to *Guidance* on page 49.

Compliance Level: 385 MHz (27 V/m); 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz (28 V/m); 710, 745, 780, 5240, 5500, 5785 MHz (9 V/m)



Note:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- If abnormal performance is observed, additional measures may be necessary, such as relocating your position, or reorienting the CP1110S Surgical Processor or accessories, before attempting the action again.





Guidance

Interference may occur in the vicinity of equipment marked with the following symbol:



Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the Surgical Processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Radio Frequency Identification

RFID uses electromagnetic fields to automatically identify and track tags attached to objects. Interference may occur in the vicinity of equipment that uses RFID readers, such as shop security, card scanners, contactless payments.



Note: The existence of fixed or mobile RFID readers may not be visible as you pass through a RF zone.





Other information

Environmental protection

Your surgical processor contains electronic components subject to the Directive 2012/19/EU on waste electrical and electronic equipment.

Help protect the environment by not disposing of your surgical processor or batteries with your unsorted household waste. Please recycle or dispose of your surgical processor according to your local regulations for electronics.

Compatible accessories

Category	Accessories
Power	Cochlear Power Extend Rechargeable Battery Module, Cochlear Y Battery Charger, Cochlear USB Power Adaptor.
Retention	Cochlear Magnet (5(I) only), Cochlear 5(I) Magnet Cover, Cochlear Earhook (M only).
Clinical	Cochlear Wired Programming Pod, Cochlear Programming Cable.

Compatible software applications

Application	Module
Nucleus SmartNav	Not applicable.
Cochlear Research Platform	Cochlear Objective Measures software.



FCC (Federal Communications Commission) compliance

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules, including part 15B for equipment classes with Unintentional Radiators. 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.

RF exposure safety

This device complies with the FCC RF exposure limits and has been evaluated in compliance with portable exposure condition.

There is no limitation as to which distance can be used from the human body.

Note:

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

These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.





Other information

FCC ID: WTO-CP1110S

Supplier's declaration of conformity

47 CFR § 2.1077 Compliance Information

Unique identifier: CP1110S

Responsible party: Cochlear Americas

10350 Park Meadows Drive
Lone Tree, CO 80124, USA

Toll free: +1 800 483 3123

Telephone: +1 303 790 9010

<https://www.cochlear.com/us>

Cochlear Ltd warrants that each unit marketed under this Supplier's Declaration of Conformity will be identical to the unit tested and found acceptable with the standards.

The devices will continue to comply within the variation that can be expected due to quantity production and testing on statistical basis.

The records maintained by the responsible party will continue to reflect the devices being produced under the Supplier's Declaration of Conformity.



ISED compliance

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with ISED license-exempt RSS(s). 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.

RF exposure safety

This device complies with the ISED RF exposure limits and has been evaluated in compliance with **portable** exposure condition.

There is no limitation as to which distance can be used from the human body.

CAN ICES-003 (B)

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

IC: 8039A-CP1110S





Other information

Labelling symbols

The following symbols may appear on the surgical processor or accessories and/or product packaging:

Symbol	Description
	Refer to instruction manual
	Consult instructions for use
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Manufacturer
	Compatible implants
	Compatible sound processors
	Authorised representative in the European Community /European Union
	Authorised representative in Switzerland
	Unique Device Identification
	Medical Device
	Catalogue number
	Serial number
	Batch code
	Date of manufacture
	Temperature limits
	CE registration mark with notified body number
	CE registration mark





Other information



Radio compliance certification for Australia and New Zealand



Radio compliance certification for Japan



Radio compliance certification for Korea

Rx Only

By prescription



Recyclable material



Dispose of electrical components in accordance with your local regulations



Type B applied part

Ingress Protection Rating

IP21

- First digit of 2: Protected against solid objects over 12mm. For example, fingers.
- Second digit of 1: Protected against vertically falling water drops.



Model number





Trademark legal notice

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントウア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, SoundBand, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

iPad is a trademark of Apple Inc., registered in the U.S. and other countries. Bluetooth is a registered trademark of Bluetooth SIG, Inc. GORE is a trademark of W. L. Gore & Associates







Notes





Hear now. And always

[AU] Cochlear Ltd (ABN 96 002 618 073)

1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352

[ECREP] [DE] Cochlear Deutschland GmbH & Co. KG

Mailänder Straße 4 a, 30539 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770

[CHREP] [CH] Cochlear AG

Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205

[US] Cochlear Americas

10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010

[CA] Cochlear Canada Inc

2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 483 3123 Fax: +1 416 972 5083

[GB] Cochlear Europe Ltd

6 Dashwood Lang Road, Bourne Business Park, Addlestone,
Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400 Fax: +44 1932 26 3426

[BE] Cochlear Benelux NV

Schaliënhoedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70

[FR] Cochlear France S.A.S.

135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National)
Fax: +33 5 34 63 85 80

[IT] Cochlear Italia S.r.l.

Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62

[SE] Cochlear Nordic AB

Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60

www.cochlear.com

[TR] Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.

Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3
Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900 Fax: +90 216 538 5919

[HK] Cochlear (HK) Limited

Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road,
Causeway Bay, Hong Kong
Tel: +852 2530 5773 Fax: +852 2530 5183

[KR] Cochlear Korea Ltd

2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450 Fax: +82 2 533 8408

[CN] Cochlear Medical Device (Beijing) Co., Ltd

Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900

[IN] Cochlear Medical Device Company India Pvt. Ltd.

Ground Floor, Platina Building, Plot No C-59, G-Block,
Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111 Fax: +91 22 6112 1100

[JP] 株式会社日本コクレア(Nihon Cochlear Co Ltd)

〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241 Fax: +81 3 3817 0245

[AE] Cochlear Middle East FZ-LLC

Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor,
Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400 Fax: +971 4 361 8925

[PA] Cochlear Latinoamérica S.A.

International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218

[NZ] Cochlear NZ Limited

Level 4, Takapuna Towers, 19-21 Como St, Takapuna,
Auckland 0622, New Zealand
Tel: + 64 9 914 1983 Fax: 0800 886 036

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