# 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.

## 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<br>GORE® cartridge: Oleophobic Polyester Blend<br>Colour: White |
| Top housing | Copolyester<br>Colour: Yellow |
| Bottom housing | Copolyester<br>Colour: White |
| Coil | Polypropylene (PP)<br>Thermoplastic elastomer (TPE) |
| Coil cable sheath | Polyvinyl chloride (PVC) |
| Coil spacer | Bormed RF830MO |
| Coil cable plugs | Polypropylene (PP) and<br>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<br>or<br>• Cochlear Research Platform Software and Cochlear Wired Programming Pod<br>• 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 |

## Surgical processing unit

| Characteristic | Value / range |
|---|---|
| Form factor | Behind the Ear (BTE) |
| Wireless data or power interfaces | • Proprietary radio–frequency (RF) link to implant<br>• 2.4 GHz connectivity data link to compatible devices<br>• Published commercial wireless protocol (Bluetooth Low Energy) |
| Wired data or power interfaces | Proprietary 6-pin (NEUF) |
| Magnets | Type: Imaging<br>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)<br>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<br>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

## 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<br>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 charcteristic 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<br>65 A/m 134.2 kHz<br>7.5 A/m 13.56 MHz | Refer to *Guidance* on page 49. |

## 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<br>**Compliance Level**: 3 V 0.15 to 80 MHz; 6 V in ISM 0.15 to 80 MHz<br>Recommended separation distance d = 1.16√P |
| **Immunity Test**: Radiated RF IEC 61000-4-3<br>**Compliance Level**: 3 V/m 80 MHz to 2.7 GHz<br>d = 0.35 √P 80MHz to 800MHz<br>d = 0.70 √P 800 MHz to 2.7 GHz<br>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).<br>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.<br>**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.

## 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.

FCC ID: WTO-CP1110S

Supplier's declaration of conformity

47 CFR § 2.1077 Compliance Information

Unique identifier: CP1110S

Responsible party: Cochlear Americas

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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

## 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 |
| EC REP | Authorised representative in the European Community /European Union |
| CH REP | Authorised representative in Switzerland |
| UDI | Unique Device Identification |
| MD | Medical Device |
| REF | Catalogue number |
| SN | Serial number |
| LOT | Batch code |
|  | Date of manufacture |
|  | Temperature limits |
| CE 0123 | CE registration mark with notified body number |
| CE | CE registration mark |

| | |
|---|---|
|  | 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 |
| **IP21** | Ingress Protection Rating<br>• First digit of 2: Protected against solid objects over 12mm. For example, fingers.<br>• 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, コントゥア, 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

# Notes

# Hear now. And always


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