

## **Safety Information for Cochlear Implant Recipients and their Carers**

Your cochlear implant device is designed to be safe and effective. It consists of both internal and external components. The implant is the internal surgically implanted part, and the sound processor is the externally worn equipment. Most cochlear implant recipients can lead a normal life but it is important that you follow the manufacturer's safety instructions.

Manufacturers are responsible for providing safety information for all their products. Device specific safety information is available from each of the manufacturers. You will be provided with a user guide for your particular device. This contains product information and essential safety information. It will inform you of any precautions or warnings or special instructions that you need to follow. It is crucial that you adhere to this advice to prevent harm to you and to avoid damage to your implant / sound processor.

The following information is for devices manufactured by **Advanced Bionics**.

Safety Information is available on the website at:

[www.advancedbionics.com](http://www.advancedbionics.com)

**Advanced Bionics** can be contacted at:

**Telephone: 01223 847 888**

**Email: [info.uk@advancedbionics.com](mailto:info.uk@advancedbionics.com)**

The British Cochlear Implant Group (BCIG) has compiled a list of frequently asked questions (FAQs) and has asked **Advanced Bionics** to provide device specific responses to these questions. BCIG does not accept liability for personal injury resulting from acts or omissions taken on the basis of the information provided.

## Cochlear Implant Safety – Frequently Asked Questions

### General Questions

Question	Answer
What should I do if I develop an ear infection?	Contact your Implant Centre and follow their advice.
What should I do if I experience pain, swelling, redness or soreness in the region of my implant?	Contact your Implant Centre and follow their advice.
What should I do if I bump my head in the region of the cochlear implant?	Contact your Implant Centre and follow their advice.
Can you provide cremation advice?	The internal device does not require to be removed prior to cremation.

### Medical and Dental Diagnostic X-Rays and Scans

Before having any type of x-ray or scan, please inform the Radiographer / Radiologist that you have a cochlear implant. You may be required to follow special instructions such as removing your sound processor to allow the scan to be carried out. [Advanced Bionics](#) has provided the following advice:

Question	Answer
Can I have a diagnostic x-ray of any part of my body?	Yes
Can I have other procedures involving x-rays e.g. dental OPT, mammogram, bone densitometry, CT scan?	Yes
Can I have a diagnostic ultrasound scan?	Diagnostic Ultrasound Energy must not be used in the area of the implant.
Can I have a Doppler ultrasound scan or echocardiogram?	Diagnostic Ultrasound Energy must not be used in the area of the implant.
Can I have Nuclear Medicine scans involving radionuclides e.g. bone scans, PET, SPECT scans?	No official recommendations. The healthcare provider should consult <a href="#">Advanced Bionics</a> with any concerns.
Can I have an MRI Scan?	<a href="#">HiRes 90K</a> Yes at 1.5T and 0.3T with the Internal Magnet removed. Countries following the EC approved claims, can use with magnet in for 1.5T when using recommended bandaging

	<p>protocol.</p> <p><a href="#">HiRes Ultra</a></p> <p>Yes at 1.5T and 3.0T with the Internal Magnet removed. Can use with magnet for 1.5T when using recommended bandaging protocol.</p>
Are there any other types of scans that could be harmful to me or my implant or require special precautions?	No

### Medical / Dental Treatments, Therapy and Surgical Procedures

Before having any medical or dental treatment, therapy or surgical procedure, please inform your Doctor, Dentist, Nurse or Therapist that you have a cochlear implant and if you have any other medical devices. Some surgical procedures and treatments that use electrical current, heat, vibration and radiation (especially in the region of the head, neck and shoulders) may be harmful to you and/or your implant. [Advanced Bionics](#) has provided the following advice:

Question	Answer
Can I undergo a course of Radiotherapy and are there any special instructions that I need to follow.	Please contact your implant centre before starting any course of radiotherapy. Your implant centre will advise you of any special instructions that you need to follow. Your general health takes priority. It is essential that you have access to any treatment that is recommended by your Oncologist. For most patients, there is <u>no</u> risk to the implant, but this will depend on the part of the body that is being treated. It is important that you remove your sound processor during treatment. The radiographer should remove it from the treatment room before each treatment session and return it to you immediately after each session.
Warnings about Electrosurgical Instruments and Diathermy	Diathermy must never be applied. Electrosurgical instruments must not be used.
Warnings about Electromagnetic Radiation	<ul style="list-style-type: none"> <li>Electromagnetic Interference (EMI):</li> </ul>

	<p>Radio Frequency (RF) workers may be exposed to higher interference. In the presence of high intensity EMI you may experience loss of sound. If this occurs, move from the area or temporarily discontinue use of the system by removing the headpiece.</p> <ul style="list-style-type: none"> <li>• Electromagnetic Sources: It is advised to maintain a minimum distance of 30 cm (12in) from electromagnetic emitters such as Radio Frequency Identification (RFID), and metal detectors. It is advised to maintain a minimum distance of 50 cm (20 in) from an electronic article surveillance emitter.</li> <li>• The HiRes Ultra implant employs an intermittently keyed back telemetry transmitter that uses a frequency modulated 10.7 MHz signal. This is a near field inductively coupled technology.</li> <li>• 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 (e.g., RFID system), it may be necessary to be at least 24" (60 cm) away to ensure proper operation. If the Naida CI Q90 EAS sound processor does not respond to the implant device because of an unusual field disturbance, move away from the disturbing field.</li> </ul>
Warnings about Therapeutic Ultrasound, Microwaves and Diathermy	Diagnostic Ultrasound Energy must not be used.
Warnings about Neurostimulation	Neurostimulators may not be used in the vicinity of the implant
Warnings about Electroconvulsive Therapy	Must never be used on a cochlear implant patient.
Are there any other medical, surgical or therapeutic treatments that could be harmful to me or my implant or require special precautions?	No official recommendations. Consult Advanced Bionics.

## Sports, Beauty and Leisure

Your cochlear implant (the inside part) is vulnerable to damage from significant bumps or falls and pressure. The implant can break or become dislodged from its original position. Surgery may be required to (re-)move the implant and replacement may or may not be possible. Cochlear implant recipients should not participate in activities where there is a high risk of head injury or sustained pressure to the implant site. For some activities, head protection may be recommended and for others, it may be advisable to remove the external equipment (sound processor and/or accessories). [Advanced Bionics](#) has provided the following advice:

Question	Answer
Are there any sports or activities that are not permitted?	<a href="#">Physical Activity: When engaging in physical activities that include the possibility of trauma or impact, precautions should be taken, such as wearing a protective helmet, to reduce the risk of damage to the internal device.</a>
Are there any sports or activities where head protection is recommended?	<a href="#">Physical Activity: When engaging in physical activities that include the possibility of trauma or impact, precautions should be taken, such as wearing a protective helmet, to reduce the risk of damage to the internal device.</a>
Can you provide advice on what type of head protection is required?	<a href="#">No official recommendations. Consult Advanced Bionics.</a>
Can I use electronic equipment for electrolysis, tattoos, pain relief, muscle toners, gym equipment etc?	<a href="#">No official recommendations. Consult Advanced Bionics.</a>
Can I use hair clippers, electrical razor, hair dryers, curling tongs, hair straighteners, head lice comb etc. in the region of my implant?	<a href="#">No official recommendations. Consult Advanced Bionics.</a>
Can I have procedures carried out that use sources of light (e.g. sun beds) or laser for hair removal, tattoo removal etc.?	<a href="#">No official recommendations. Consult Advanced Bionics.</a>
Warnings about Fairground Rides and Amusement Parks	<a href="#">No official recommendations. Consult Advanced Bionics.</a>
Warnings about Extreme Thrill Rides and other activities with High G Forces	<a href="#">No official recommendations. Consult Advanced Bionics.</a>
Warnings about Swimming, Snorkelling, Shallow Diving, Canoeing and Sailing	<a href="#">The Implant is tested to continue working at up to a depth of 138ft (HiRes Ultra) and 33ft (HiRes 90k) without a sound processor nor</a>

	with a Neptune or Naida sound processor in an AquaCase protective cover.
Warnings about Scuba Diving	Implant tested to depth of 138ft (HiRes Ultra) and 33ft (HiRes 90k)
Are there any other sports, recreational activities or cosmetic procedures that could be harmful to me or my implant or require special precautions?	When engaging in any physical activities that include the possibility of trauma or impact, precautions should be taken, such as wearing a protective helmet, to reduce the risk of damage to the internal device.

### At Home, Education and in the Workplace

You are very unlikely to come across any equipment in your home that has the potential to interact or cause damage to your implant. However, warnings are in place for those working with high powered electrical equipment and electromagnetic radiation in the workplace or in places of education. [Advanced Bionics](#) has provided the following advice:

Question	Answer
Should I be concerned about static electricity at home, in the car, in the office, children's play equipment (ball pools etc.) and are any precautions required?	It is known that static electricity can potentially damage sensitive electronic components such as the ones used in the cochlear implant system. Care should be taken to avoid situations in which high levels of static electricity are generated. See caution information about Electrostatic Discharge (ESD) in User Guide
Is there any standard household equipment that has potential to interact with my implant, processor or accessories and are any precautions required? e.g. induction hobs.	Using or being in close vicinity to someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. See warnings about Electromagnetic Radiation
Is there any equipment at school, college or university (e.g. in science, technical subjects or home crafts) that has potential to interfere or interact with my implant, processor or accessories and are any precautions required? e.g. Van der Graaf generators.	Using or being in close vicinity to someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. See warnings about Electromagnetic Radiation
Is there any equipment in the workplace that	Using or being in close vicinity to someone

has potential to interact with my implant , processor or accessories and are any precautions required?	using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. See warnings about Electromagnetic Radiation
Warnings about high-voltage equipment, radar, high tension wires, smelting furnaces etc.	To avoid interference electrical field strengths should be less than 3 V/m in frequency ranges over 150 kHz to 80 MHz. Note: A field strength of 1 v/m represents a potential difference of one volt between points separated by one meter. Any electrically charged object produces an electric field. This field has an effect on other charged objects in the vicinity. The field strength at a particular distance from an object is directly proportional to the electric charge on that object. See warnings about Electromagnetic Radiation above.
Warnings about electro-magnetic radiation.	See warnings about Electromagnetic Radiation and MRI limitations above.
Are there any other signals or systems that could be harmful to me or my implant or require special precautions?	No official recommendations. Consult Advanced Bionics.
Can you provide advice for those who are required to wear a Hard Hat in the work place?	No official recommendations. Consult Advanced Bionics.

### **Interactions and Interference**

In everyday life it is very rare for other equipment to interact or interfere with your sound processor or wireless technology. If this happens you may experience intermittent or distorted sound. It will not damage your processor and the effect is only temporary. It will go away when you move away from the source of interference. Do not remain close to the source of interference for any longer than necessary (or switch-off your processor in advance). It is equally unlikely that your cochlear implant, sound processor or wireless technology will affect the functionality of nearby electrical equipment. If this happens, move away from the affected electronic device. You may be asked to switch-off your processor or wireless technology in restricted

areas where radio frequency transmission is prohibited. [Advanced Bionics](#) has provided the following advice:

Question	Answer
<p>Are there any known sources of interference that may interact with my cochlear implant and accessories and are there any precautions that I should follow?</p>	<p><a href="#">See warnings below</a></p>
<p>Do my cochlear implant or accessories have the potential to interact or cause interference in other electrical equipment nearby and are there any precautions that I should follow?</p>	<p><a href="#">See warnings about Electromagnetic Radiation above.</a></p> <p><a href="#">Ultrasonic Sensors</a>            Ultrasonic sensors, sometimes used in lighting sensors and security systems, will not damage your implant system; however, they may be picked up by the headpiece microphone and lead to distorted sound quality when you operate your sound processor in the immediate vicinity of such a sensor. Additionally, if the ultrasonic sound is of a very high intensity, the processor system microphone may become damaged. To avoid hearing any unwanted sound, you should reduce the volume on your sound processor or remove your headpiece when passing near an ultrasonic sensor (e.g. in entrances to libraries). <a href="#">See User Guides</a></p>
<p>Can my cochlear implant and accessories interact with any other medical devices that I have? e.g. cardiac pacemaker or any electro-medical equipment that I rely upon e.g. insulin pumps, dialysis equipment etc.</p>	<p><a href="#">No official recommendations. Consult Advanced Bionics.</a></p>
<p>Can my cochlear implant and accessories interact with medical devices in use by others in close proximity e.g. can a young CI user feed/sleep on the chest of an adult pacemaker user?</p>	<p><a href="#">No official recommendations. Consult Advanced Bionics.</a></p>
<p>Are there any situations where I should switch-off my processor or wireless technology e.g. going through airport security, on planes during take-off and landing, in hospital intensive care units?</p>	<p><a href="#">Metal detectors, x-ray machines, and security scanners will not damage the implant or sound processor. However, individuals with a cochlear implant should be advised that passing through security metal detectors may activate the detector alarm. It is advised that patients carry their "Patient</a></p>

	<p>Emergency Identification Card” with them at all times. Cochlear implant users also might hear a distorted sound caused by the magnetic field around the security scanner door or hand-held scanning wand. Turning the sound-processor volume down before passing through security screening will ensure that those sounds, if they occur, are not too loud or uncomfortable.</p> <p>X-ray machines will not damage your sound processor or implant, but may damage your head piece or microphones. Avoid placing any system microphones in any checked or carry-on baggage that is screened with X-ray. During airport security screenings, the sound processor and microphone should be worn through the metal detector or examined by hand. See Cautions in User Guide and warnings about Electromagnetic Radiation</p>
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**This document was prepared in November 2017 and is due for review in November 2019. If you have any further questions regarding safety, please do not contact BCIG. Always contact your cochlear implant centre and/or Advanced Bionics in the first instance.**