



Medicines & Healthcare products
Regulatory Agency

Guidance

Medical devices: sources of electromagnetic interference

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1. Overview

Electromagnetic interference (EMI) can affect several types of medical devices that have electrical or electronic systems. Examples of devices that can be affected include:

- pacemakers or defibrillators – implanted or external
- implanted neurostimulators
- programmable hydrocephalus shunts
- cochlear implants
- ECG monitors
- infusion pumps

Manufacturers of medical devices are required to minimise the risk that their device can cause, or be affected by, EMI. Where the risk is not eliminated, the manufacturer must include information about the residual risk in the instructions for use.

One route to show compliance with the regulations is to use standards. For example EN 60601-1-2 'Electromagnetic disturbances — Requirements and tests' is commonly used to show compliance of non-implantable equipment. As this is a medical device harmonised standard, its use also infers a measure of compliance with the regulations.

This standard has a requirement to include 'recommended separation distances' in the instructions for use. This lists safe distances by power output and transmitter frequency band.

We recommend that hospitals/trusts develop local policies to minimise the risk of interference with critical medical equipment. This may require a review of the instructions for the device and equipment.

There are many sources of EMI in hospitals and healthcare environments but the ones most likely to cause problems with certain medical devices include:

- emergency vehicle/services radios
- diathermy (electro-surgery)
- mobile phones
- radiofrequency identification (RFID) devices
- electromagnets

2. Emergency vehicle/services radios

These types of radios are used in emergency service vehicles, including ambulances.

Radio communications emit strong electromagnetic waves and pose the highest risk of EMI with sensitive medical devices.

This means you should determine if sensitive equipment is used in the buildings close to parked ambulances. You should also:

- carry out a risk assessment before sensitive medical devices are used inside an ambulance and repeat the assessment if there are any changes to the vehicle radio system
- position external pacemakers as far as possible from the vehicle's aerial(s); there should be a warning notice inside the ambulance to show the position of the aerial(s)
- train ambulance, paramedic, cardiac and accident and emergency staff to recognise common interference events, and act appropriately

The new Emergency Services Network ([ESN](https://www.gov.uk/government/publications/the-emergency-services-mobile-communications-programme/emergency-services-network#about-the-emergency-services-network) (<https://www.gov.uk/government/publications/the-emergency-services-mobile-communications-programme/emergency-services-network#about-the-emergency-services-network>)) uses 4G technology and so the risks are more comparable to those presented by mobile phones.

3. Diathermy (electro-surgery)

This can affect active devices such as:

- implanted pacemakers
- cardioverter defibrillators
- cochlear implants

Interference generated by monopolar surgical diathermy is more severe than that generated by bipolar diathermy and can be sufficient to temporarily inhibit pacemaker output, cause a temporary increase in pacing or cause a loss of programmed settings.

4. Mobile phones

We do not recommend a ban on the use of mobile phones in hospitals. However, a mobile phone can affect sensitive equipment when it is operated at high power in close proximity to the device.

Mobile phone power output varies with signal quality from a few mW up to the maximum of 1-2 W when signal quality is poor.

Therefore, we recommend that hospitals/trusts develop local policies to reduce the risk of interference to critical devices.

5. Radiofrequency identification systems

Radiofrequency identification (RFID) devices are used in healthcare establishments to trace and track equipment. They can also be used in a patient's hospital bracelet.

RFIDs consist of 2 parts: a tag (which may be active or passive) and a detector ('reader'). They are becoming more commonly used.

The level of interference from RFIDs is similar to that from mobile phones. They may cause problems with sensitive electronic medical devices such as pacemakers and monitors if they are closer than 1 metre.

Hospitals/trusts should do a risk assessment before using this technology and will need to decide on areas of restriction. We recommends caution; avoid using these technologies in critical care areas such as intensive therapy units (ITU), special care baby units (SCBU) or where patients are attached to complex devices.

The risk of interference from RFIDs is influenced by:

- type or power output of the reader
- type or power rating of the tag (active tags only)
- carrier frequency
- distance between reader and medical device
- location of use: in a store room there is a low or no risk, in an operating theatre the risk is higher

6. Airport security

We are not aware of any interference problems between security body scanners and sensitive medical devices such as:

- implanted pacemakers
- implanted cardioverter defibrillators (ICDs)
- neurostimulators
- infusion pumps/ glucose monitors

People with these implants should walk through metal detectors normally and not wait in the detection zone. Airport security body scanners use high-frequency electromagnetic waves to scan a body. These electromagnetic waves pass through clothing and are reflected by the skin. They do not enter the body and so would not interfere with implanted electronic medical devices.

Some infusion pumps and glucose monitoring devices should not be exposed to X-ray screening systems and whole-body scanners. However, this advice differs between different manufacturers therefore, users are advised to check before travelling.

Patients should carry their device registration card to show to staff when passing through security checks.

6.1 Hand Held screening.

Hand-held screening wands can interfere with implanted devices and a distance of 15cm should be kept between them. Exposure to screening wands should be limited and security personnel should only pass the wands very quickly over the device whilst, maintaining the safety distance. Failure to do so could result in inappropriate therapy being delivered to a patient.

7. Non-EMI interference

The functions of active devices such as implanted pacemakers, cardioverter defibrillators and cochlear implants can be affected by fixed magnets. They can interfere by activating the magnetic reed-switches of the device.

Small, fixed magnets are in a range of objects such as:

- headphones
- security tags on clothes in shops
- fastenings on mobile phone cases, clothes and jewellery

The effects can cause asynchronous mode pacing in pacemakers and inhibition of shock therapy in implantable defibrillators.

The risk is negligible as long as the item isn't put too close to the implant (ie not closer than 3cm). So for example, headphones should not be placed in the breast pocket of a shirt or jacket, or draped around the neck, even when not in use.



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