BRITISH HEART RHYTHM SOCIETY GUIDELINES FOR THE MANAGEMENT OF PATIENTS WITH CARDIAC IMPLANTABLE ELECTRONIC DEVICES (CIEDs) AROUND THE TIME OF SURGERY

Honey Thomas, Andy Turley and Chris Plummer
on behalf of BHRS Council - January 2016

Revision to the document made - February 2019

INTRODUCTION

The use of Cardiac Implantable Electronic Devices (CIEDs) for rhythm management include pacemakers for control of bradycardias, implantable cardioverter defibrillators (ICDs) for treatment of life-threatening ventricular tachycardias, biventricular or resynchronisation pacemakers and ICDs for treatment of heart failure using ventricular resynchronisation (CRT-P and CRT-D respectively), implantable loop recorders(ILRs) and insertable cardiac monitors (ICMs) for monitoring cardiac arrhythmias.

These devices fall into 3 categories:

1. ILRs and ICMs which allow for targeted ECG monitoring

2. Cardiac pacemakers – single lead, dual lead or biventricular

3. ICDs–single lead, dual lead or biventricular

The presence of these devices may present a problem when procedures are carried out in which the patient may be exposed to electromagnetic interference (EMI) leading to inappropriate device function. Precautions therefore need to be considered prior to these procedures for the correct management of CIED patients.

This document is intended to provide practical guidance to use when patients with CIEDs need to undergo surgical intervention, expanding on the MHRA guidance published in 2006[1]. This guidance also includes advice regarding common diagnostic procedures. It is recognised that there is limited trial data to guide clinicians in some areas and most evidence is in the form of expert opinion. This document will be reviewed by BHRS on a bi-annual basis.

BACKGROUND: CIEDs AND ELECTROMAGNETIC INTERFERENCE

Pacemakers and ICDs are highly sophisticated electronic medical implants designed to treat abnormal slow or fast heart rhythms in response to electrical signals within the heart.

Both pacemakers and ICDs have been designed with a high degree of tolerance to electrical and magnetic interference fields and special filtering components have been incorporated to minimise the effects of these. A problem may arise, however, if the energy level of a nearby field is very high, or has a frequency component that is close to that generated by the heart. This may have a variety of effects on the function of the CIED which may lead to inhibition of a pacemaker, induction of fixed rate pacing, software reset or triggering of shocks in an ICD patient. Electromagnetic interference (EMI) by most types of fields usually only interferes transiently with device function and when the interference ceases, the device returns to normal. Only very powerful fields are likely to have any permanent effects on device or lead function (e.g. gamma radiation or very strong magnetic fields).

ICDs are designed to treat arrhythmias such as ventricular tachycardia or ventricular fibrillation; hence there is the possibility that the electromagnetic interference may be misinterpreted as a ventricular arrhythmia causing inappropriate initiation of anti-tachycardia therapy or delivery of shocks.

Where a CIED uses an impedance-based rate responsive pacing function (e.g. a minute ventilation sensor), interference from diathermy or manipulation of the device can be sensed by the implant resulting in inappropriate high rate pacing. Temporarily programming the device to a non-rate response mode (prior to surgery) will prevent this.
Manufacturers of implantable pacemakers and ICDs either contraindicate the use of surgical diathermy/electrocautery, or give strong warnings against its use – especially the unipolar (most commonly used) mode of operation.

However, where surgical diathermy/electrocautery is essential and is to be used at a site remote from the implanted device, then there is a low risk of an effect on the device which may lead to inappropriate function. The use of bipolar surgical diathermy/electrocautery should be considered (in preference to unipolar) wherever possible, although there are still small risks attached to this.

Implantable loop recorders and insertable cardiac monitors, monitor cardiac signals and there is no risk to the patient with any surgical procedure. The device may interpret electromagnetic interference as a rapid heart rhythm and record an episode of tachycardia but this will be apparent when the device in interrogated. No additional precautions are needed for patient with an ILR/ICM. However, it may be useful to interrogate the device before the procedure and clear the diagnostic memory after the procedure in case the memory becomes saturated with episodes of detected EMI.

PLANNED SURGICAL PROCEDURES IN PATIENTS WITH CIEDs

Patient screening

Since the majority of surgical procedures are planned in advance, patients having these devices should be identified through pre-admission screening. Although the pre-admission process may request patients to declare if they have a pacemaker/ICD, this should be independently verified and noted in the records. Patients with these devices are usually provided with a registration card recording details of the device and its manufacturer.

Appendix 1 shows an example of a flow chart which can be used to clearly identify lines of responsibility and communication, particularly to cardiac physiologists, when such patients are identified prior to elective surgery.

Recording pacemaker/ICD details
When a pacemaker/ICD is identified it should be clearly recorded by the surgical/procedural assessment staff in the patient's notes and marked for the attention of key clinical staff. Prior to surgery the anaesthetist and surgeon involved should be aware of the implications of the patient having a CIED.

Where possible the following key information should be noted for future reference (and will be available via the patient's usual hospital pacing clinic):

- Type of device and manufacturer (pacemaker/ICD/ ILR / ICM)
- Implanting hospital, follow-up hospital
- Date of last follow-up
- If the device is at or approaching replacement
- If the device is part of a clinical investigation where restrictions may apply
- Device location (CIEDs are usually implanted in the left or right pre-pectoral region; however, some devices may be located in the left lateral chest wall (subcutaneous ICDs) and very rarely the abdomen. Device location will be relevant in considering the implications of the procedure)

The patient's follow-up clinic will be able to:

- Confirm the correct functioning of the pacemaker/ICD and to check the condition of the battery and leads etc. prior to surgery. Additional checks are not required providing follow up is not overdue
- Advise if adjustments to sensing/pacing parameters are required (the majority of devices will not require changes prior to or after surgery)
- Advise whether an ICD needs to be programmed off prior to surgery and the local logistics for this. If deactivation is carried out, it should be done immediately prior to surgery with a review to reactivation as soon as practical.

Considering additional peri-procedural support
At the time of the procedure, the following should be considered when surgical diathermy/electrocautery or other devices with potential EMI are to be used on patients having a CIED:

- Monitoring the patient's ECG from the outset of the procedure (some monitors may give inaccurate readings of paced beats so if in doubt check the patients pulse and/or use pulse oximetry)
- Availability of external defibrillation equipment, external temporary pacing and cardio-pulmonary resuscitation
- For patients where the ICD is deactivated and where access to the anterior chest wall will interfere with surgery (or the sterile field), consider connecting the patient to an external defibrillator using remote pads. Defibrillator pads should be positioned as far away from a CIED as possible (see figure 1)

- Where diathermy/electrocautery is unavoidable, limit its use to short bursts and ensure that the return electrode is anatomically positioned so that the current pathway between the diathermy electrode and return electrode is as far away from the pacemaker/defibrillator (and leads) as possible

- If detectable pacemaker inhibition occurs, the surgeon should be informed immediately and diathermy either used intermittently or discontinued
- If device programming has been altered then patients may need to have ECG monitoring until their device parameters have been restored to pre-op settings and the ICD is reactivated. This should be done as soon as practical and ideally the same day.

Guidance for Specific Procedures

The following tables are a suggested guide for required actions in different clinical situations. There is relatively little evidence for specific types of surgery.[1,2,3] These tables represent an attempt to provide practical guidance for common situations based on a consensus of expert opinion, the limited available data and device manufacturers information. *ICD deactivation is best carried out by formal deactivation with a programmer by a cardiac physiologist or cardiologist. Magnet deactivation is only acceptable in emergency situations where deactivation is not possible/feasible.

General Surgery (including dermatology if diathermy used)

	Pacemaker	**ICD**
Surgery site: lower abdomen, lower limbs or upper arms distal to the elbow	Monitor during surgery to ensure no inhibition of pacemaker. No reprogramming of the device likely to be required. No post op device checks required unless programming has been altered or an adverse event has occurred	Deactivation* of ICD during surgery and reactivation post operatively
If surgery in head, neck, upper abdomen or upper limb proximal to the elbow	Monitor to ensure no inhibition of pacemaker. Consider pacemaker reprogramming only if pacing dependant and prolonged diathermy close to device. No post op device checks required unless programming has been altered or an adverse event has occurred	Deactivation* of ICD during surgery and reactivation post operatively

Cardiac Surgery

Pacemaker	**ICD**
Programming highly likely to be required during most cardiac operations. Perform full check post op	Deactivation* of ICD during surgery and reactivation post operatively

Ophthalmic Surgery

	Pacemaker	**ICD**
If unipolar diathermy anticipated	Monitor during surgery to ensure no inhibition of pacemaker. No post op device checks required unless programming has been altered or an adverse event has occurred	Deactivation* of ICD during surgery and reactivation post operatively

Endoscopy Procedures

Pacemaker	ICD
Monitor during procedure. No action required unless pacing dependant and prolonged diathermy/argon beam anticipated. No post op device checks required unless programming has been altered or an adverse event has occurred	Deactivation* of ICD may be appropriate if prolonged diathermy/argon beam anticipated and reactivation post operatively

Dental Surgery

Pacemaker	ICD
No action required unless diathermy use is anticipated. No post op device checks required unless programming has been altered or an adverse event has occurred	Deactivation* of ICD may be appropriate if diathermy is anticipated and reactivation post operatively

Lithotripsy

General measures as described above for patients who are undergoing diathermy should be followed.

Pacemaker	ICD
Avoid focussing beam near the pulse generator. If lithotripsy triggers on R wave consider disabling atrial pacing during treatment	
Interrogate device within one month after treatment	Deactivation* of ICD during the procedure and carry out checks and reactivation after the procedure

Electroconvulsive Therapy

General measures as described above for patients who are undergoing diathermy should be followed.

Pacemaker	ICD
Interrogate device within one month after treatment	Deactivation* of ICD during the procedure and carry out checks and reactivate immediately after procedure

Nerve Conduction Studies (Electromyography, EMG)

General measures as described above are recommended. The risk of interaction with a CIED is low but is raised if repetitive rather than single stimuli are applied and if the stimuli are applied to the proximal arm ipsilateral to the device.[4,5]

Pacemaker	ICD
Monitor to ensure no inhibition of pacemaker. Consider pacemaker reprogramming only if pacing dependant and repetitive nerve stimulation close to device. No post op device checks required unless programming has been altered or an adverse event has occurred	Deactivation* of ICD may be appropriate if repetitive nerve stimulation is anticipated with reactivation post procedure

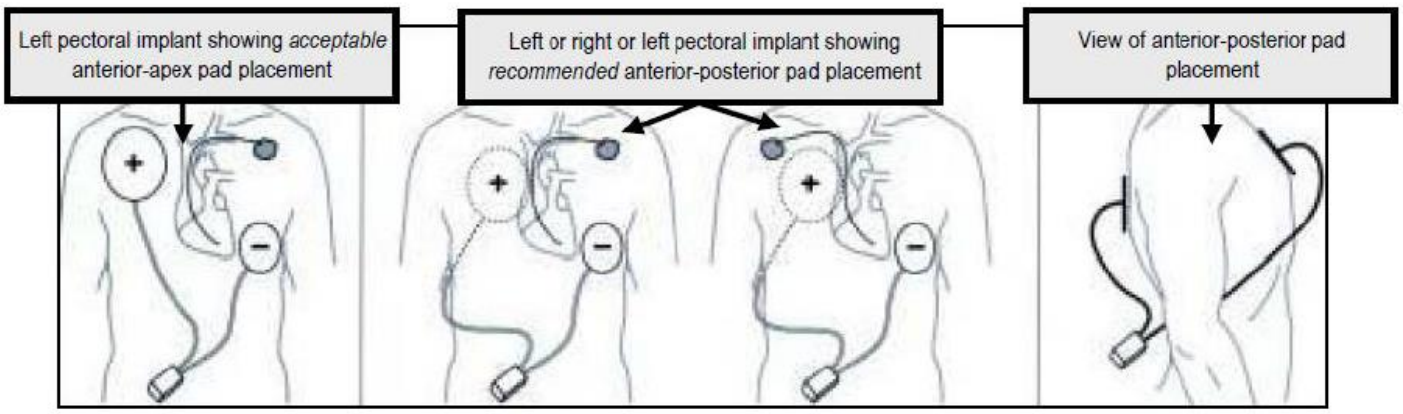
EMERGENCY PROCEDURES

Wherever possible, the steps outlined above should be followed when handling emergency cases. Ensure that cardio-pulmonary resuscitation and the ability to perform temporary pacing in accordance with ALS guidance are available.

CARDIAC ARREST

In the case of cardiac arrest, resuscitation should be carried out in the same way as if there were no device. This is regardless of the programmed functionality of the device at the time of the arrest. There is no significant risk to someone performing CPR or touching the patient even if a shock is delivered by the patient's ICD. If an external shock is needed in a patient with an implantable device, defibrillation pads should be positioned as far away from the device as possible and ideally in the antero-posterior position (see fig 1). Energy from external defibrillation can damage an implantable device and if the resuscitation attempt is successful then the device should be interrogated afterwards to confirm its function.

Figure 1: Recommended positioning of defibrillation pads in patients with implantable devices.



MAGNETS AND CIEDs

Implantable devices respond to placement of a magnet positioned immediately over them in a variety of ways. The response to the presence of a magnet in both pacemakers and ICDs is only temporary and normal function will resume as soon as the magnet is removed.

Pacemaker Magnet Response

Most pacemakers respond with fixed rate (asynchronous) pacing while a magnet is held over the generator. While this can be useful in rare situations where pacing is inhibited by diathermy, leaving a magnet over the pacemaker is not generally recommended. The asynchronous pacing can occasionally be arrhythmogenic (R on T phenomenon).

ICD Magnet Response

For ICDs, placing a magnet over the device will inhibit delivery of anti-tachycardia pacing and shock therapy but will have no effect on bradycardia pacing.

For patients with ICDs, if arrangements cannot be made to deactivate the device then consideration may be given to positioning a clinical magnet over the implant site to inhibit inappropriate shock delivery. Clinical magnets for this application will be available from the local cardiac pacing centre along with instruction for correct use. Magnets should also be available from coronary care units and local guidelines should be in place to detail their locations.

For the purposes of this document, a magnet refers to a specifically designed ring or block magnet, which should be available in all hospitals. Ring magnets should be positioned over the implantable device. It may be necessary to feel for the device as it may have migrated away from any visible implant scar. The majority of manufacturers of the ICDs implanted in the UK (Medtronic, Boston Scientific and Biotronik) advise positioning the magnet directly over the device. However, St Jude Medical recommends that the magnet is offset from the device with the curve of the ring magnet positioned over the top or bottom of the device (see figure 2). LivaNova (formerly Sorin) advise that with their devices, the magnet should be positioned off centre avoiding the header at the top of the device. In the majority of clinical situations, a magnet placed directly over the ICD will be effective at withholding shock therapy.

Figure 2. Correct positioning of a ring magnet to deactivate therapies of a St Jude Medical ICD

However, it should be noted that:

- The use and function of the magnet must be fully understood and acknowledged
- Inhibition of shock delivery will only be effective during magnet placement and that this should be secured to the patient for the duration of surgery using surgical tape. Magnets can easily shift position and they need to be positioned correctly. If the surgical procedure is prolonged (>8 hours), one manufacturer's ICDs (Biotronik) will revert to normal function, in which case the magnet needs to be removed and then re-applied.
- Any subsequent VT/VF will need to be treated using external defibrillation equipment. Consider attaching any ICD patient who has a deactivated device to the external defibrillator using hands free pads.

In the event of a prolonged, life-threatening arrhythmia, conventional advanced life support procedures should be followed. An ICD may emit an audible alarm / beep / vibration when close to a strong magnetic field or when a magnet is applied over the generator.

Surgical Magnetic Drapes and CIEDs

Caution should be exercised when using magnetic drapes to hold surgical equipment as these may cause magnet effects in the implanted cardiac device[7]. Placement of magnetic drapes on the patient thorax should be avoided. The use of bottom-isolated magnetic drapes may reduce the risk of interaction with the implanted device.

RADIOTHERAPY

Background

Pacemakers and ICDs (cardiac implantable electronic devices or CIEDs) may sustain damage or have their functionality affected by a course of radiation therapy. Radiotherapy beams may damage the device battery and/or circuitry causing malfunction. The risk of malfunction generally increases with dose. The delivery of radiotherapy may also lead to electromagnetic interference (EMI) which can lead to similar device sensing problems to those described with diathermy. This may lead to inhibition of pacing therapy or an inappropriate shock with an ICD.

There are no detailed national or international guidance documents in this area. There is very little robust scientific data to reliably inform decisions about how to manage CIEDs in the setting of modern radiotherapy techniques and most guidance is based on consensus opinion.[1,2,3,6] A recent publication in Europace[6] details the latest expert consensus opinion.

REFERENCES

1. MHRA guidelines for the perioperative management of patients with implantablepacemakers or implantable cardioverter defibrillators, where the use of surgical diathermy/electrocautery is anticipated. http://bhrs.com/files/files/Guidelines/Guidelines for the perioperative management of patients with implantable pacemakers or ICDs where the use of surgical diathermy is anticipated.pdf

2. Practice Advisory for the Perioperative Management of Patients with Cardiac Implantable Electronic Devices: Pacemakers and Implantable Cardioverter-Defibrillators. An Updated Report by the American Society of Anesthesiologists Task Force on Perioperative management of Patients with Cardiac Implantable Electronic Devices. *Anesthesiology* 2011; **114:** 247-61.

3. Beinart R, Nazarian S. Effects of external electrical and magnetic fields on pacemakers and defibrillators: from engineering principles to clinical practice. *Circulation* 2013; **128:** 2799-809.

4. Ohira M, Silcox J, Haygood D, Harper-King VJ, Alsharabati M, Lu L, Claussen G, Oh S. Nerve conduction studies in patients with implanted devices are safe regardless of magnet placement. *Clinical Neurophysiology* 2012; 123: e67-e68.

5. Cronin EM, Gray J, Abi-Saleh B, Wilkoff BL. Safety of repetitive nerve stimulation in patients with cardiac implantable electronic devices. *Muscle Nerve* 2013; **47:** 840-4.

6. Zaremba T, Jakobsen AR, Søgaard M, Thøgersen AM, Riahi S. Radiotherapy in patients with pacemakers and implantable cardioverter defibrillators: A literature review. *Europace*2015; doi:10.1093/europace/euv135.

7. Zaphiratos V, Chiasson H, Drolet P, Benzaquen B, Lapointe J, Fortier LP. Interference between surgical magnetic drapes and pacemakers: an observational study comparing commercially available devices and a new magnetically isolated drape. BioMedical Engineering OnLine 2016; 15:83.

APPENDIX 1: EXAMPLE OF A PERI-OPERATIVE CARDIAC DEVICE FLOW CHART: ELECTIVE SURGERY