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

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INTRODUCTION

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

These devices fall into 3 categories:

1) Implantable loop recorders and implantable cardiac sensors s which allow for targeted ECG monitoring
2) Cardiac pacemakers – single lead, dual lead, biventricular or leadless
3) Implantable cardioverter defibrillators (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 safe management of CIED patients.

This document is intended to provide practical guidance for patients with CIEDs undergoing surgical intervention, expanding on the BHRS guidance first published in 2006. This guidance also includes advice regarding common diagnostic procedures and dental interventions. 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 biannual basis.

Important changes since last revision

- Pre-surgery remote device follow up should be regarded as equivalent to in person follow up in patients with normal functioning devices
- The guidance recognises that temporary magnet deactivation and programming off therapies are both acceptable methods of deactivation of defibrillators
- Responsibility for patients remains with the clinical team responsible for the episode of care (rather than cardiac physiologists and cardiology teams). The clinical team is responsible for re-activating devices which have been deactivated by programming
- Surgery below the umbilicus may not require ICD deactivation
- Dental procedures are included and use of ultrasound de-scalers is not anticipated to cause problems with cardiac devices
- Inclusion of magnetic surgical drapes, anchoring and guidance systems and capsule endoscopy

BACKGROUND: CIEDs AND ELECTROMAGNETIC INTERFERENCE (EMI)

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 pacing, induction of fixed rate pacing, inappropriate rapid pacing, software reset or triggering of shocks in an ICD patient. Most types of EMI interfere only 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). Potential sources of EMI in the surgical setting include diathermy/electrosurgery, nerve stimulators, transcutaneous electrical nerve stimulation (TENS) machines, radiofrequency scanners for surgical instrument detection and radiofrequency ablation devices.

Pacemaker sensing of EMI may inhibit appropriate pacing as the device wrongly interprets EMI as intrinsic cardiac rhythm. This is most concerning in those patients who are pacing dependant and do not have any underlying rhythm. In addition, 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, although this is unlikely to lead to any clinical harm.

ICDs are designed to treat arrhythmias such as ventricular tachycardia or ventricular fibrillation; hence there is the possibility that the EMI may be misinterpreted as a ventricular arrhythmia causing inappropriate initiation of anti-tachycardia therapy or delivery of shocks. Inappropriate shocks from an ICD are associated with increased mortality and it is therefore vital that these are avoided, even if an anaesthetised patient would be unaware of them[1]. In addition, associated unanticipated patient movement associated with shock delivery may be harmful during surgery.

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, is to be used at a site remote from the implanted device and the electrodes are positioned appropriately (see below), then there is a low risk of any effect on the device which may lead to inappropriate function. The use of bipolar surgical diathermy/electrocautery should be considered (in preference to monopolar) wherever possible, although there are still small risks associated with this.

Implantable loop recorders (ILR) and insertable cardiac monitors (ICM), monitor cardiac signals and there is no risk to the patient with any surgical procedure. The device may interpret EMI 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 a patient with an ILR/ICM. However, it may be useful to interrogate the device electively before, and clear the diagnostic memory after the procedure, in case the memory is filled with episodes of detected EMI.

PACING DEPENDANCY

Patients receive CIED therapy for different reasons. The presence of pacing stimulation artefacts on an ECG does not mean that the patient is pacemaker-dependent (that their heart rhythm requires a stimulus from the pacemaker).

Permanent pacemaker: Implanted to treat slow heart rhythms (bradycardia). These devices are programmed to promote intrinsic cardiac activity and as such pace only when the heart rate falls below a pre-set level, typically 60 bpm.

Implantable cardioverter defibrillators (ICD): Implanted to treat patients who have suffered, or are at high-risk of suffering, from a ventricular arrhythmia. These patients typically do not have an indication for a permanent pacemaker and the devices are usually programmed to pace the heart only if the heart rate is less than 40 bpm.

Cardiac resynchronisation therapy (CRT): Implanted to treat patients with heart failure. These devices work by co-ordinating ventricular contraction and as such are programmed to pace the heart continuously.

WiSE-CRT system

The WiSE-CRT system uses an ultrasound transmitter with a separate battery unit, both of which are implanted in the chest wall to stimulate a "seed" (small ultrasound-sensitive electrode) situated in the left ventricle. The manufacturer advises specific precautions regarding this device. Currently, this technique has been used in a small number of patients and the implanting centre should be contacted prior to any procedures for advice. See Appendix 2 for more detailed information.

Leadless pacemaker: Leadless pacing systems may be implanted in a small number of patients (typically the Micra single-chamber transcatheter pacing system (Medtronic, Minneapolis, MN). These devices are small and implanted directly into the cardiac muscle. They typically pace the heart when the heart rate drops in a similar way to a conventional system. Advice regarding potential EMI effects is similar to conventional devices with leads.

The prevalence of pacemaker dependency in a CIED population is determined by the definition used. The Heart Rhythm Society defines pacemaker dependency as no intrinsic rhythm greater than 40 bpm or haemodynamic instability with the intrinsic rhythm[2]. In clinical practice a patient is pacing dependent when they have an inadequate or absent intrinsic heart rhythm, which becomes symptomatic if there is a (sudden) failure of the CIED's pacing function. A frequently used definition is the absence of any spontaneous ventricular activity (or the presence of low-rate, clinically not tolerated, spontaneous activity when the CIED is transiently programmed in VVI 30-40 bpm)[3]. The majority of patients are not pacing dependent based on this definition, and as such, if their device was temporarily turned off or damaged, they would not come to serious harm or death from sudden CIED failure[4]. Cessation of diathermy results in return of pacing.

Pacing dependant patients are at greater risk from EMI inhibition of their pacing function and, if prolonged diathermy is anticipated in proximity to the device, reprogramming to a fixed rate pacing mode should be considered (see below).

PLANNED SURGICAL PROCEDURES IN PATIENTS WITH CIEDs

Patient screening

Since the majority of surgical procedures are planned in advance, patients with 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 in the patient's notes by the surgical/procedural assessment staff 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/CRT/ILR /ICM)
- Implanting hospital, follow-up hospital
- Date of last follow-up
- If the device is at or approaching battery depletion
- 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 is relevant when 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 preoperative checks are not required providing regular follow-up is not overdue. The device clinic undertaking follow up of the device will be able to provide advice.
- Advise if adjustments to sensing/pacing parameters are required (the majority of devices will not require changes prior to or after surgery, see below).
- Advise if ICD deactivation may be required. If a patient has an ICD there are 2 options for deactivation (see below). Local follow up centres should have a standard operating procedure which will detail the option of either temporary magnet deactivation or reprograming the device to prevent shock therapy.

Many devices are now under remote follow-up, and device interrogation may be possible without the need for the patient to attend the clinic face to face. Remote threshold checks are equivalent to in-clinic tests, thus a patient with stable lead parameters does not need an additional in-person check prior to surgery if the parameters are fine on remote monitoring. If reprogramming is required, it is not possible to do this via the remote systems, and patients must be seen face to face.

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 with 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), and never directly over the device (pulse generator) itself.
- Where diathermy/electrocautery is unavoidable, limit its use to short bursts at the lowest feasible energy level. Use bipolar diathermy if possible. Teams should 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. Underbody electrodes are not recommended[5].
- If detectable pacemaker inhibition occurs or there is evidence of ICD therapy being delivered, the surgeon should be informed immediately and diathermy either used intermittently for short bursts or discontinued. Magnet application can be considered if this isn't possible (see below).
- If device programming has been altered for a surgical procedure, patients need to have ECG monitoring until their device parameters have been restored to pre-op settings and/or the ICD is reactivated. This should be done as soon as practical and ideally in the recovery room. Responsibility for arranging this remains with the treating clinical team (not cardiac physiologists).

Guidance for Specific Procedures re CIED programming/interrogation

The following table is a suggested guide for required actions in different clinical situations. There is relatively little evidence for specific types of surgery[2,6,7]. 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. There is evidence that EMI is more likely to affect device function if it is used near the pulse generator or leads. Typically, this occurs in surgery performed superior to the umbilicus, but is not likely during procedures below the umbilicus[5, 8-12]. Therefore, in procedures below the umbilicus, it is reasonable not to carry out ICD deactivation/pacemaker reprogramming. However, a magnet should be immediately available for emergency use. Post-op checks are usually not required unless programming has been altered.

If ICDs are disabled for surgery, it is important to ensure that they are enabled after surgery. Failure to re-enable tachycardia therapies after surgery will leave ICD patients without

protection from ventricular arrhythmias which could result in their death. If ICDs are to be programmed off for surgery, surgical departments must have procedures in place to ensure the devices are returned to normal operation as soon as practicable after procedures, and that checks are in place to ensure patients will not be discharged to an unmonitored environment, or even home, without this having taken place. Responsibility for arranging this remains with the treating clinical team (not cardiac physiologists or cardiologists).

*Suspension of ICD treatment can be achieved by either (1) deactivation of the device by a member of the cardiac team using a programmer or (2) by temporary application of a clinical magnet. There are practical advantages and disadvantages to these approaches. Deactivation is a more definite approach which ensures guaranteed suspension of therapies or programming changes. However, it requires input from the cardiac team before and after surgery (which can be challenging logistically), and whilst the device is awaiting reactivation, it will not treat potentially serious arrythmias. Magnet deactivation is an alternative and is recommended in emergency situations or where programmer deactivation is not feasible. Magnet application is available where cardiac physiologists are not on site, and reduces the risk that patients fail to have therapies turned on after surgery. A potential disadvantage of magnet deactivation is that the magnet may be positioned inappropriately or move unintentionally away from the device - this may not be easily apparent when the magnet is placed. In this case, anti-tachycardia therapies may be delivered inappropriately. See below for advice if prolonged magnet application is anticipated for Biotronik devices. Centres should have a standard operating procedure in place to guide which approach for device deactivation is used and how this is accessed.

Table: Management of CIEDs during interventional procedures

<table>
<tr><th></th><th colspan="2">Pacemaker</th><th colspan="2">Implantable Defibrillator</th></tr>
<tr><th></th><th>Pacing dependant</th><th>Not dependant</th><th>Pacing dependant</th><th>Not dependant</th></tr>
<tr><td>Surgery above umbilicus</td><td>Consider reprogramming to fixed rate if prolonged diathermy anticipated</td><td>Monitor during surgery to ensure no inhibition of pacemaker. No reprogramming</td><td>Deactivation* of ICD & consider reprogramming to fixed rate pacing
Or
Magnet application only if prolonged diathermy not anticipated.</td><td>Deactivation* of ICD
Or
Magnet application</td></tr>
<tr><td>Surgery below umbilicus</td><td>Monitor during surgery to ensure no inhibition of pacemaker. No reprogramming. Clinical magnet should be available</td><td>Monitor during surgery to ensure no inhibition of pacemaker. No reprogramming</td><td colspan="2">Monitor during surgery to ensure no inhibition of pacemaker or inappropriate therapies. Reasonable not to deactivate ICD. Clinical magnet should be available</td></tr>
<tr><td>Cardiac surgery</td><td colspan="2">Reprogramming likely to be required</td><td colspan="2">Deactivation* of ICD +/- reprogramming during surgery</td></tr>
<tr><td>Eye surgery</td><td colspan="4">As for general surgery if monopolar diathermy is used</td></tr>
<tr><td>Endoscopy (see below for magnetic anchor guidance)</td><td>Consider reprogramming to fixed rate if prolonged diathermy or argon beam anticipated</td><td>Monitor during procedure to ensure no inhibition of pacemaker. No reprogramming</td><td>Deactivation* of ICD & consider reprogramming to
fixed rate pacing if diathermy/argon anticipated
Or
Magnet application only if prolonged diathermy/argon not anticipated.</td><td>Deactivation* of ICD if diathermy/argon anticipated
Or
Magnet application</td></tr>
<tr><td>Dental</td><td colspan="4">No action required unless diathermy in use</td></tr>
<tr><td rowspan="2">Lithotripsy</td><td colspan="2">Interrogate device within one month after treatment</td><td colspan="2">Deactivation* of ICD during therapy session
Or
Magnet application</td></tr>
<tr><td colspan="4">Avoid focussing beam near the pulse generator. If lithotripsy triggers on R wave consider disabling atrial pacing during treatment</td></tr>
</table>

Electro-convulsive therapy	Interrogate device within one month after treatment		Deactivation* of ICD during procedure ***Or*** Magnet application	
Nerve conduction studies (if repetitive, prolonged and close to device)[13,14]	Consider reprogram to fixed rate	Monitor during procedure to ensure no inhibition of pacemaker. No reprogramming	Deactivation* of ICD & consider reprogramming to fixed rate pacing ***Or*** Magnet application **only** if prolonged stimulation not anticipated	Deactivation* of ICD. ***Or*** Magnet application

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[13]. 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.

Magnetic Anchoring and Guidance Systems

Magnetic anchoring and guidance systems are used in laparoscopic and endoscopic surgical procedures to provide traction and control in the surgical environment using an external magnet to manipulate and internally positioned instrument[14,15]. These systems require the use of a powerful external magnet. There is no direct data of the effect of these systems on CIEDs, but it is likely that device therapy would be affected by the magnet itself[16] in addition to potential EMI, and the system manufacturers contraindicate their use in patients with these devices. In selected patients, it may be possible to programme a device to mitigate some of this risk, but in general these magnetic systems are not recommended in patients with CIEDs.

Capsule Endoscopy

It has been suggested that there may be a theoretical risk of EMI with capsule endoscopy, but European guidance and a review of the available literature show no evidence of any clinical risk to the patient[17,18]. Image quality may rarely be affected.

Dental Procedures & ultrasonic cleaning

There has been conflicting evidence regarding potential interactions between CIEDs and a variety of dental devices. There is no clear and widely accepted national or international guidance. Reports have been largely based on in vitro studies of patients with older generation cardiac devices and often older generation dental equipment. Newer cardiac devices are designed to minimise the effects of EMI.

The latest evidence would suggest that at a distance of at least 15 cm, interference from ultrasonic scalers, apex locators, pulp testers and drills, is not likely to pose any clinical risk to cardiac device patients.

Operators should avoid draping any leads/cords across the patient. In addition, using the devices for short bursts minimises any potential risk. The manufacturers of the most widely used cardiac devices in the UK support this conclusion in their literature (Medtronic, Biotronik, Boston scientific, Abbott/St Jude Medical). Patients with implantable devices should be carefully observed during dental procedures. If EMI were to cause inhibition of the pacemaker causing any symptoms, or if the device were to beep or vibrate, prompt cessation of use of the dental tool and moving it away from the patient will allow normal device function to resume. Therefore, if use of the dental equipment would have appreciable benefits for the patient's dental outcome, then this is likely to outweigh any small theoretical risks to their cardiac device. Electrocautery/diathermy does carry potential risk to pacemaker and ICD patients and the advice outlined above in the wider surgical guidance should be carefully followed.

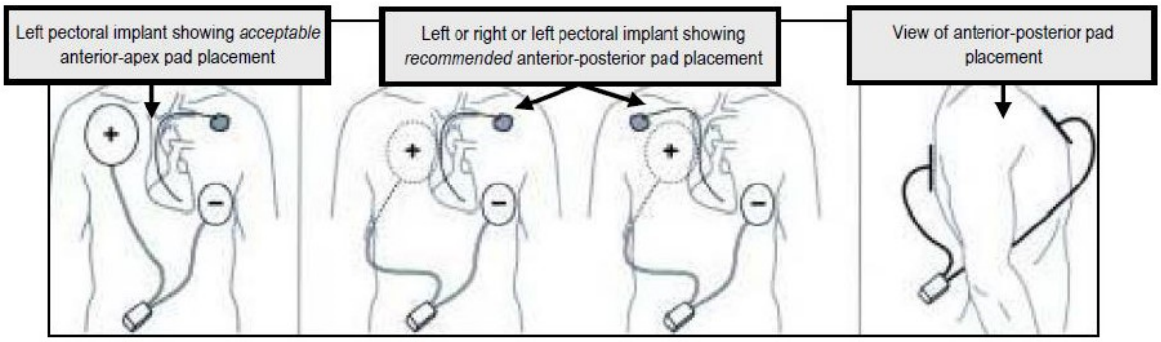
EMERGENCY PROCEDURES

Wherever possible, the steps outlined above should be followed when emergency surgery is required. Ensure that cardio-pulmonary resuscitation and the ability to perform temporary pacing in accordance with ALS guidance are available. See below for guidance re magnets.

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 as possible from the device, and ideally in the antero-posterior position (see Fig 1). Energy from external defibrillation can damage an implantable device, so 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. Magnets can easily move out of a functioning position and do not provide a reliable or individualised modification of device programming. The advantage of magnet application is the simplicity, the lack of need to reprogram the device after procedures (avoids the possibility of failure to reprogram ICD therapies back on) and this is also practical at sites which do not have on site cardiac physiology.

Pacemaker Magnet Response

Most pacemakers (simple and resynchronisation) 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 in patients with an underlying intrinsic cardiac rhythm (R on T phenomenon).

Leadless pacemakers do not respond to magnets with fixed rate pacing and therefore any programming changes need to be carried out using the specific device programmer. If this isn't possible, particularly in a pacing dependant patient, caution should be used.

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.

Magnet application may be considered, 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/Abbott 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 correct 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.
- 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.

In the event of a prolonged, life-threatening arrhythmia, conventional advanced life support procedures should be followed.

The BHRS is developing guidance of arrhythmias and devices in pregnancy.

Additional contributions from Paul Foley & Ian Wright

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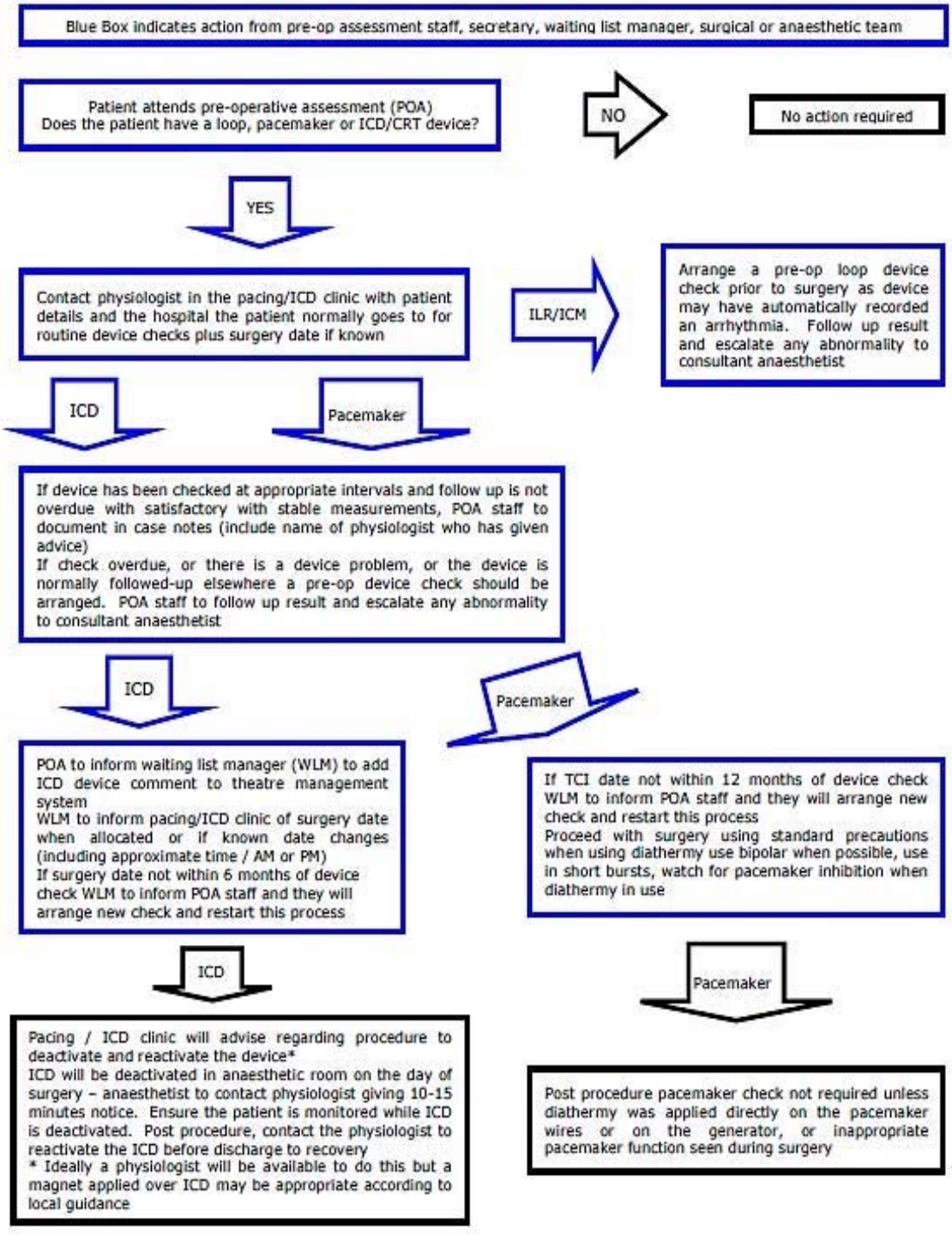
APPENDIX 1: EXAMPLE OF A PERI-OPERATIVE CARDIAC DEVICE FLOW CHART: ELECTIVE SURGERY



Appendix 2: WiSE-CRT System[19]

The WiSE-CRT System provides leadless, LV, endocardial pacing to provide CRT. When paired with a conventional pacemaker or ICD, it replaces the pacing function of the CS lead. A Transmitter is connected to a Battery unit, which are both implanted subcutaneously in the chest wall. The Transmitter sends a focused beam of ultrasonic energy to a Receiver Electrode implanted on the LV endocardium, which converts the ultrasound into electrical energy and stimulates the cardiac tissue.

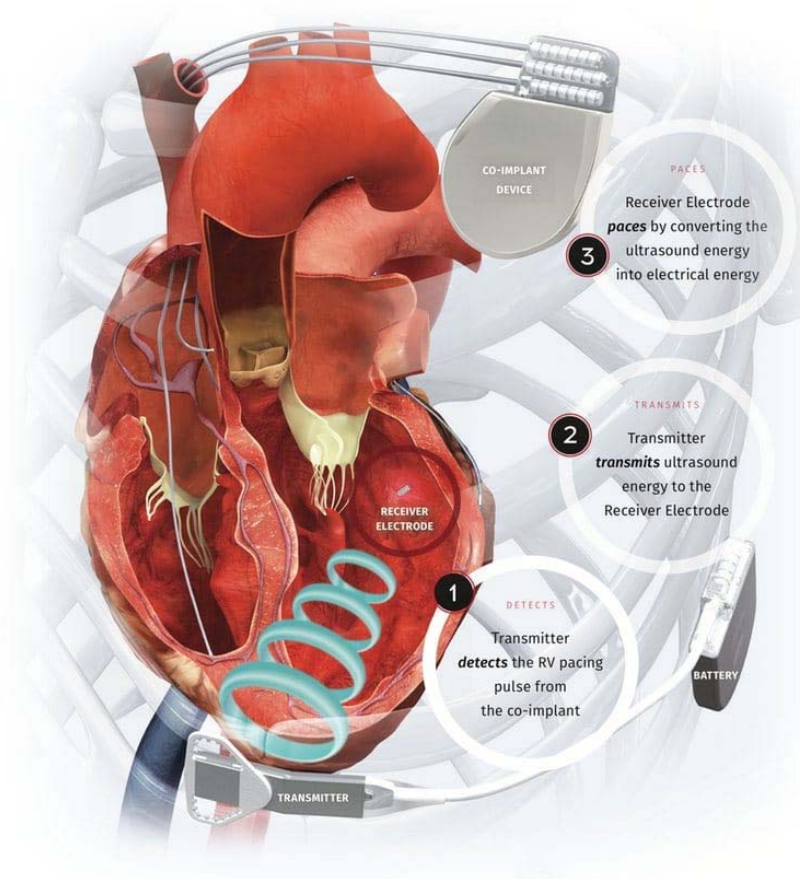


Figure 3: Diagram illustrating components of the WiSE CRT system.

The manufacturer advises the following specific precautions:

- Ultrasound -Imaging directly targeting the Electrode should be avoided, and echocardiography should be undertaken with reduced power settings (<1.9MI). Avoid exposure to high intensity ultrasound (e.g. lithotripsy or therapeutic ultrasound).
- Diathermy and Radiation therapy - Avoid direct exposure over the Transmitter, Battery and Electrode.
- External Defibrillation - Where possible, avoid placing pads / paddles directly over Transmitter and Battery.
- Re-programming co-implant device - Physiologists should be cautious about re-programming the RV pulse width of the co-implant devices of patients implanted with WiSE-CRT as this may result in the inhibition of the WiSE-CRT LV pacing.