Mid Essex Hospital Services NHS
NHS Trust

Management of Cardiac Implantable Electronic Devices (CIED) and Elective Surgical Procedures (Pacemakers & ICDs)	**Type: Clinical Guideline** **Register No: 09004** **Status: Public**

Developed in response to:	MHRA Guidelines
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Consulted With	**Post/Committee/Group**	**Date**
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Signed Off for: **1. Professional Approval** **2. Clinical Effectiveness** **3. Usability**	 Dr Clesham Dr Kath Rowe	 19/07/2017 19/07/2017

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Author/Contact for Information	Michelle Colton-Goff/Rebecca Teesdale/Stacey Mayes
Policy to be followed by (target staff)	All Staff Involved in the Care of Patient with ICD's in Elective Surgery – particularly Pre-assessment/Anaesthetics/Theatre Staff/Cardiac Physiologists
Distribution Method	Intranet & Website
Related Trust Policies (to be read in conjunction with)	04072 – Hand Hygiene Policy 04071 – Standard Infection Prevention Precautions 04070 – Decontamination of Equipment and Environment Policy 04001 – Equality and Diversity Policy 13003 – Carers Policy

Document Review History

Version Number	**Authored/Reviewed by**	**Active Date**
1.0	Gemma Goodren, Chief Cardiac Physiologist	7th December 2009
2.0	Michelle Colton-Goff/Rebecca Teesdale/Stacey Mayes	25 Sept 2017

Contents

1. Purpose

1.1 To provide guidance and support to all relevant medical staff who are responsible for the care of patients with Cardiac Implantable Electronic Devices (CIED) in situ at the time of preparation for elective surgical procedures, both in the pre-assessment and surgical settings.

1.2 To provide clarity and direction regarding the process to be followed for the preparation of care for patients with CIEDs when being considered for and during elective surgical procedures, to provide safe and effective care.

2. Equality and Diversity

2.1 The trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.

3. Definition/Background

3.1 The use of Cardiac Implantable Electronic Devices (CIEDs) for heart rhythm management include:

- Pacemakers for control of bradycardia (slow heart rates)
- Implantable Cardioverter Defibrillators (ICDs) for treatment of life-threatening ventricular tachycardias (fast heart rates)
- Biventricular or Resynchronisation Pacemakers/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

3.2 Despite already having a high degree of tolerance to electrical and magnetic interference fields, it is still possible for CIEDs to encounter problems 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. Possible effects on the function of the CIED include:

- Inhibition of a pacemaker
- Induction of fixed rate pacing
- Software reset
- Triggering of shocks in an ICD
- Thermal heating at the lead/tissue interface

3.3 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).

Therefore, precautions need to be considered when procedures are carried out in which the patient may be exposed to electromagnetic interference (EMI). Failure to

plan the management of these devices may lead to inappropriate device function and cause harm.

4. Scope

4.1 This clinical guidance applies to any patient who has a Cardiac Implantable Electronic Device (CIED) in situ and requires, or is being considered for, elective surgery.

5. Staffing and Training

5.1 The Anaesthetic Consultant is responsible for:

- Being aware and compliant with this clinical guidance.
- Ensuring they have adequate and appropriate training and understanding before requesting/making the decision that a patients device may require reprogramming.
- Ensuring that the Cardiac Physiology team is informed of the plan to reprogram the device. This can be done by completing the Device Reprogramming Request Form (Appendix 2), and returning it to the Cardiac Centre in a timely and appropriate manner.
- Ensuring that adequate information about the need and consequences for device reprogramming is communicated to the patient and/or family, and consent obtained.
- Liaising with the Cardiac Physiology Team regarding the Reprogramming, including contact on the date of the procedure and informing of any changes made to procedure.
- Ensuring they have adequate and appropriate training before using external defibrillation equipment in the event of an emergency.
- Ensure the WHO checklist includes details of the patient's device and plan to reprogram.

5.2 **In the event where the procedure does not require Anaesthetic team involvement (i.e. local anaesthetic only procedures), then the Consultant Surgeon holds ultimate responsibility for ensuring staff follow this document**.

5.2 Cardiac Physiologists deemed competent in follow-up management of CIEDs are required to:

- Be aware and compliant with this clinical guidance.
- Ensure they have the correct information about the device manufacturer, model and mode.

- Ensure that the appropriate programmer is available for the date and time of device reprogramming.
- Ensure that any changes made to any device are recorded fully and appropriately on the Cardiology reporting system (Tomcat).

6. Infection Prevention

6.1 All staff will adhere to Trust guidelines on infection prevention at all times; such as hand washing, the use of sterile procedures, and additional infection prevention measures when required i.e. gloves and aprons and effective decontamination of all non-disposable equipment between patients.

7. Clinical Instruction –Pre Procedure (Patient Identification)

7.1 All patients for elective surgical procedures should be pre-assessed.

7.2 All patients with a CIED in situ should be pre-assessed by a consultant regardless of whether the procedure is to be performed under Local or General Anaesthesia due to the clinical risk and preparation required. **Patients of this nature should not be preassessed in a Nurse-Led Pre-assessment Clinic, in line with ASA Guidelines.**

7.3 The Anaesthetic Consultant at pre-assessment should clarify the type of CIED in situ and assess the need for reprogramming (see appendix 1 for guidance).

7.4 Considerations to be aware of:

- **Diathermy:** Patients with CIEDs in situ are ideally treated with bipolar electrosurgery. The short current pathway reduces the likelihood of current interfering with the device. Where monopolar must be used, the current pathway should be kept as short as possible by placing the return electrode as close to the surgical site as is possible, away from the location of the device. **Electrosurgery should be stopped immediately in the event of an arrhythmia.**

- **Harmonic Scalpels:** The use of high frequency vibrations, as opposed to current being introduced to the body, poses very little risk to patients with CIEDs in situ. However, it is necessary that direct contact with the device is avoided at all costs. No programming changes are advised.

7.5 When the need for device reprogramming has been identified, the Device Reprogramming Request Form (Appendix 2) should be completed and returned to Cardiac Centre A210 or emailed to mie-tr.mehtpacingicd@nhs.net.

7.6 Once Identified and the Device Reprogram Request Form is fully complete, a copy of the patient's last device follow up should be obtained by the preassessment team from the patient's follow up centre and securely attached to the Request Form.

7.7 **Where possible, patients requiring device reprogramming should be placed 1st on the theatre operating list to allow adequate time for device changes to take place within the working hours of the Cardiac Physiology Team.**

7.8 Completed request forms should be delivered to the Cardiac Centre (A210) to Lorraine Argent (Cardiology Waiting List Coordinator). All requests will be date stamped on arrival. Contact extension number 4209 or 4185.

8. Clinical Instruction – Pre Procedure

8.1 The Anaesthetic Consultant is responsible for ensuring the Cardiac Department is contacted to confirm that the procedure is to be performed as planned, with an estimated start time, and has not been cancelled on the day. **In the event where an Anaesthetist is not present (i.e. local anaesthetic only procedures) then this responsibility lies with the Consultant Surgeon.**

8.2 If the Date or Time of the TCI is changed it is the responsibility of the Anaesthetic Consultant to ensure the Cardiac Physiology Team is informed of the changes as soon as possible. **In the event where an Anaesthetist is not present (i.e. local anaesthetic only procedures) this responsibility lies with the Consultant Surgeon.**

If this is short notice it may not be guaranteed that a Cardiac Physiologist will be available.

8.3 It is the responsibility of the Anaesthetist to contact the Cardiac Department (Extension 4209 or 4185) once the patient has been sent for, and to confirm the theatre number in which the Cardiac Physiologist is required. **In the event where an Anaesthetist is not present (i.e. local anaesthetic only procedures) this responsibility lies with the Consultant Surgeon.**

A minimum of 15 minutes' notice should ideally be given of patients' arrival.

8.4 All relevant equipment should be available in the anaesthetics room and ready for use, to include:

- 3 Lead ECG
- Pulse Oximeter
- External Defibrillator with Pacer Capability (if patient has an ICD in situ)

8.5 No Anaesthesia should be given until the Cardiac Physiologist is in attendance.

8.6 Prior to anaesthesia being given, the External Defibrillator, 3 Lead ECG and Pulse Oximeter should be attached to the patient.

8.7 If the patient has an ICD in situ, and therapies have been requested to be deactivated, external defibrillation pads should be placed ideally in the Anterior/Posterior position in case of the need for External Transcutaneous Pacing.

If this is not possible due to the location of surgery, then pads should be placed in a location appropriate to the surgery to allow for an effective defibrillation vector, whilst being at least 15cm away from the CIED to minimise interference and damage to the generator should defibrillation be required.

9. Clinical Instruction – Cardiac Physiologist

9.1 The attending Cardiac Physiologist will explain the procedure and reasoning behind the need for any changes to be made to the CIED and to confirm that the patient is aware and happy to proceed.

9.2 The attending Cardiac Physiologist will ensure the current settings/parameters of the device are accurately recorded prior to any changes being made.

9.3 Any required changes to the CIED will be made and communicated to the patient and theatre staff, and documented in patient notes, where required.

9.4 The attending Cardiac Physiologist is responsible for ensuring correct and accurate documentation of any changes that are made to the device on the Cardiology reporting system (TOMCAT), including the attachment of the Request/Consent Form to the patient's file.

10. Clinical Instruction – During Procedure

10.1 Theatre Staff should closely monitor the patient's haemodynamics throughout the procedure and in the event of a life threatening arrhythmia occurring treat the patient using normal Advanced Life Support (ALS) protocols.

11. Clinical Instruction – Post Procedure

11.1 Once the procedure is complete, the patient must remain attached to the ECG monitoring, external defibrillator (if patient has ICD in situ) and have 1:1 nursing care, until the Cardiac Physiologist has attended and the CIED has been reprogrammed to previous settings. The 1:1 nurse must have ALS competency.

11.2 Once the device has been reprogrammed post procedure, theatre staff may detach any defibrillator pads, external defibrillator and monitoring from the patient, unless required for another specified purpose.

11.3 The attending Cardiac Physiologist will document any changes made to the device on the Cardiology reporting system (TOMCAT), and in patients notes, where required.

12. Emergency 'out of hours' CIED Reprogramming

12.1 There are situations where emergency device reprogramming is required outside of normal working hours (9-5pm Monday to Friday). If deactivation by a Cardiac Physiologist is not available, for emergency procedures only, a magnet can be applied directly over the generator site.

12.2 Medical staff should obtain verbal consent following communication to the patient/family including the reasons and consequences for magnet use:

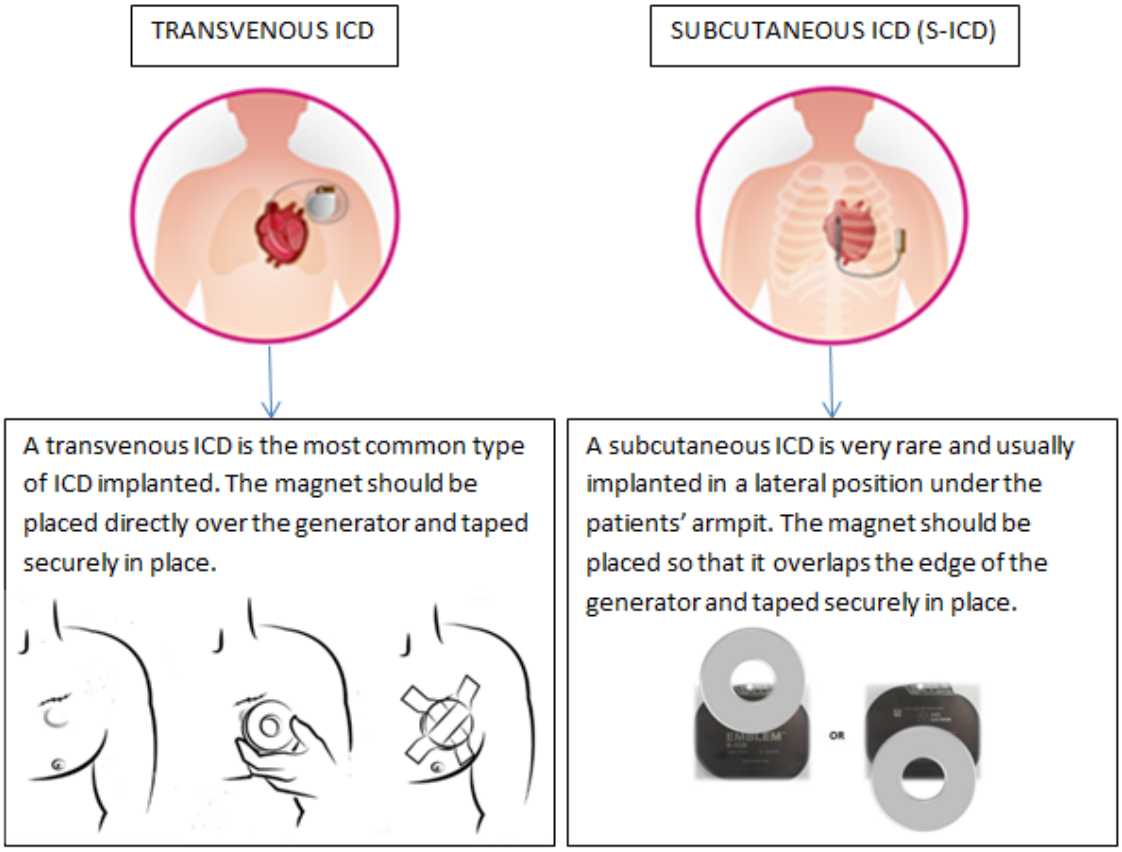
- The response to the presence of a magnet in both pacemakers and ICDs is only temporary and normal function will resume as soon as the magnet is removed.

12.3 Magnet Response:

- **Pacemakers** respond to magnet application with fixed rate (asynchronous) pacing. While this can be beneficial 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), therefore magnet therapy is generally only recommended for patients who are dependent on their pacemakers.

- **ICDs** respond to magnet application with the inhibition of anti-tachycardia pacing and shock therapy. **Magnet application has no effect on bradycardia pacing in ICDs.**

12.4 There are two main types of ICD; trans-venous and subcutaneous. Please see the following diagram to identify these types and correctly apply a magnet.



12.5 Magnets can be obtained from the following locations:

- Cardiac Centre
- Theatres
- Terling Ward (A305)
- Bed Office
- Palliative Nurses (community)

12.7 Some devices are only inhibited by a magnet for 8 hours; therefore the magnet should be removed for 30 seconds and then reapplied every 7 hours.

14.0 Breach Reporting

14.1 In the event that this guidance is not followed, a risk event form should be completed via the Datix System.

15.0 Audit and Monitoring

10.1 This document will be reviewed annually and when new clinical guidance is issued. ICD deactivation request procedure compliance will be monitored to ensure that guidance is being adhered to, and any significant concerns will be raised via DATIX reporting.

10.2 Incidences and complaints will be reviewed every 3 months by a Senior Cardiac Physiologist and results will be reported to the Principal Physiologist.

16.0 References

Boston Scientific (2015) 'S-ICD Magnet Use'

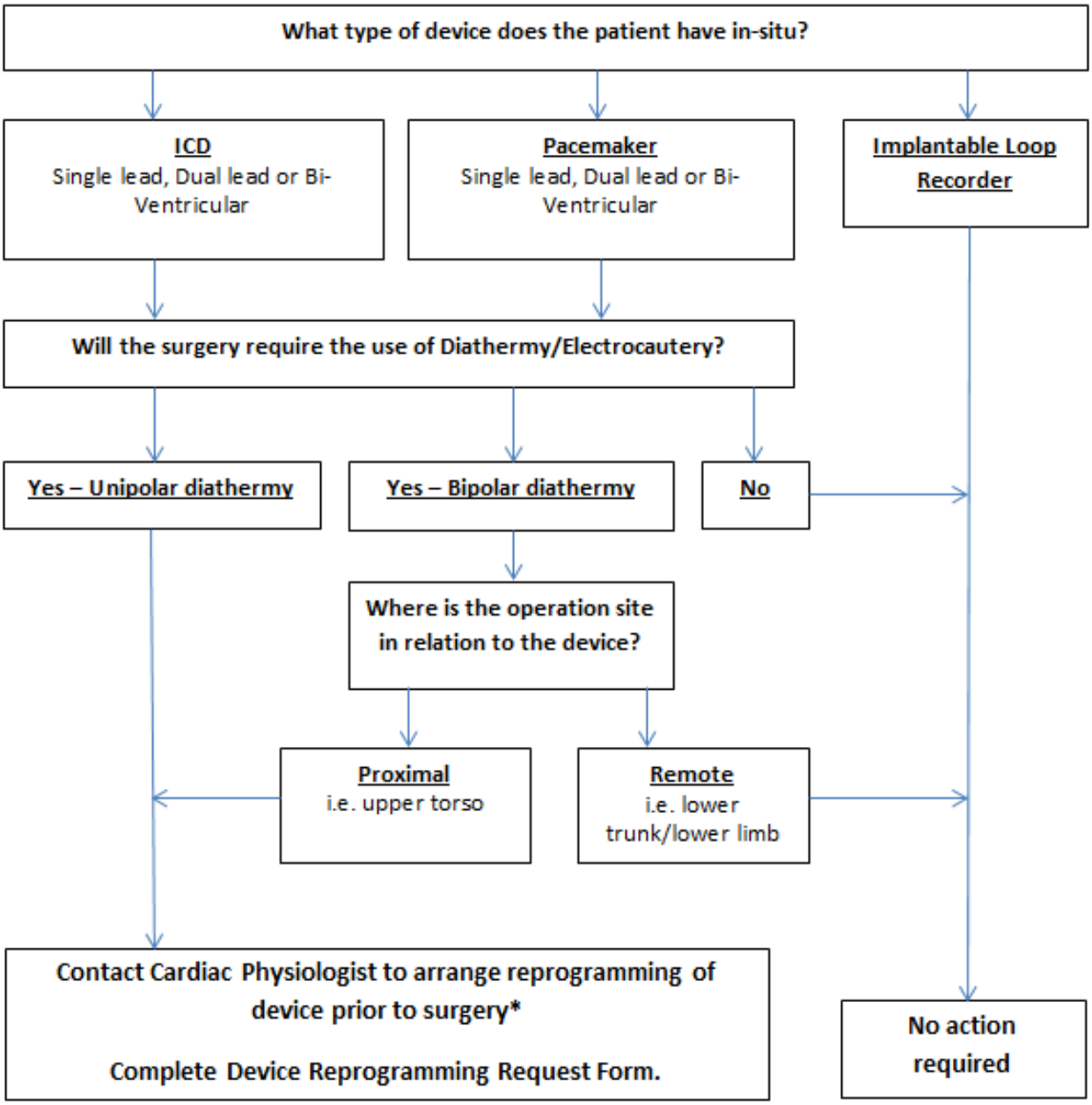
Available at: https://www.bostonscientific.com/content/dam/bostonscientific/quality/education-resources/english/US_ACL_SICD_Magnet_Use_20150413.pdf Boston Scientific (2016) *'Emblem S-ICD System – Subcutaneous Implantable Defibrillator'*

Available at: http://www.bostonscientific.com/en-US/products/defibrillators/emblem-s-icd-system/device-overview.html

British Heart Rhythm Society (BHRS) (2016) Thomas, H., Turley, A., Plummer, C.

'Management of Patients with Cardiac Implantable Electronic Devices (CIEDs) Around The Time of Surgery'

Appendix 1 - Peri-operative Management of Cardiac Implantable Electronic Devices (CIEDs) in Surgery



*Cardiac Physiology Service is available between 08:00-18:00 Monday to Friday. Outside these hours, please follow protocol for emergency procedures.

Please ensure you have the following information available prior to completing the request form and/or speaking to the Cardiac Physiology Team:

- Device manufacturer, model and serial number
- Implant/follow-up centre & details of most recent check
- Date and type of procedure/operation

Appendix 2 – Device Reprogramming Request Form

This form is to be completed at pre-assessment. Please complete all fields in block capitals.

Patient details
Surname:
Forename:
DOB:
MEHT Hospital Number:
NHS Number:

Date & Time of Request:
Name of Requester:
Designation:
Contact Number/Extension/Bleep number:

Intended Procedure: **Please include site of surgery*	
Date & Time of Procedure:	
Diathermy to be used?	Yes-Bipolar / Yes-Unipolar / No

Device Manufacturer/Model:	
Device follow-up centre & date of last check: **Please attach a copy of last follow-up report*	

I confirm that the following has been discussed with the patient and/or family:

- The need and consequences for the device to be reprogrammed before and after the procedure (this may include temporary deactivation of shock therapy).
- The reassurance that the patient will be appropriately monitored throughout the procedure to ensure patient safety (this may include constant monitoring via external defibrillator).
- Patient and/or next of kin consent has been obtained.

Signature of authorising Consultant/Physician:	
Print name:	
Date:	

Please return completed form to Cardiac Centre A210 or email to mie-tr.mehtpacingicd@nhs.net

Any queries, please contact the Cardiac Centre on extension 4185

Appendix 3 - Equality Impact Assessment (EIA)

Mid Essex Hospital Services NHS
NHS Trust

Title of document being impact-assessed:

Management of Cardiac Implantable Electronic Devices (CIED) and Elective Surgical Procedures (Pacemakers & ICDs)

Equality or human rights concern	Does this item have any differential impact on the equality groups listed? Brief description of impact.	How is this impact being addressed?
Gender	All identified patients requiring Elective Surgical Procedure/Cardiac Device reprogramming will be treated the same irrespective of their gender.	Staff communication is encouraged to support all patients. Staff will ensure that dignity for all patients is maintained regardless of gender. All complaints will be fully investigated and responded to.
Race and ethnicity	All identified patients requiring Elective Surgical Procedure/Cardiac Device reprogramming will be treated the same irrespective of their race and ethnicity.	The Trust operates within the requirements of The Race Equality Act 2010. Language may be a barrier; however staff should plan in advance for an interpreter to be present during the procedure or use relative/carers to assist with translation if necessary, wherever possible.
Disability	It is acknowledged that some patients requiring Elective Surgical Procedure/Cardiac Device reprogramming may have/live with physical disabilities, learning disabilities, autism or other mental health issues.	Patient information should always be accessible and up to date. All areas have disabled access such as wheelchairs, lifts and toilets. In patients with sensory impairment or sensitivities extra care will be taken to explain every step of the procedure to the patient including the use of different materials that may touch their skin to avoid distress.
Religion, faith and belief	All identified patients requiring Elective Surgical Procedure/Cardiac Device reprogramming will be treated the same irrespective of their beliefs.	There is access to the multi faith chaplaincy team who offer advice and support for patients, relatives, carers and staff.