Doncaster and Bassetlaw Hospitals NHS
NHS Foundation Trust

Deactivation of Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronisation Therapy (CRT) Devices Procedure

This procedural document supersedes: PAT/T 55 v.1 – Deactivation of Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronisation Therapy (CRT) Devices Procedure

Did you print this document yourself?
The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

Author/reviewer: (this version)	Vivienne Hayward – Chief Clinical Physiologist
Date written/revised:	09/10/2014
Approved by:	Policy Approval and Compliance Group
Date of approval:	26 November 2014
Date issued:	2 December 2014
Next review date:	September 2017
Target audience:	Trust-wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 2	2 December 2014	• References updated • Appendix 1 updated • Amended to new style APD Template (new branding)	Vivienne Hayward
Version 1	December 2011	• This is a new procedural document, please read in full.	Vivienne Hayward

Contents

1. INTRODUCTION

Implantable Cardioverter Defibrillators (ICDs) are implanted in patients at risk of developing life threatening ventricular arrhythmias. Many of these patients have associated heart failure and coronary heart disease. Patients with left ventricular dysynchrony may be implanted with a Cardiac Resynchronisation Therapy device which may have a defibrillation function (CRT-D).

The purpose of an ICD is to continuously monitor heart rhythm and respond to arrhythmias. An ICD may provide automatic defibrillation therapy to terminate fast ventricular fibrillation (VF) or fast ventricular tachycardia (VT), anti-tachycardia pacing to terminate slow VT, cardioversion of VT and anti-bradycardia pacing where required.

Heart failure tends to be a progressive illness and is a leading cause of death. Patients approaching end of life with end-stage heart failure or another illness frequently exhibit metabolic or biochemical disturbances and are at risk of developing complex agonal rhythms that may trigger defibrillation. Shocks experienced during the dying phase would disturb the patient and cause distress. In such situations it may be inappropriate to maintain the ICD in active defibrillation mode.

The anti-bradycardia pacing functions of such devices should NOT be disabled as withdrawing pacing support may cause symptoms and accelerate the dying process.

2. PURPOSE

Patients with an ICD or CRT-D are regularly followed up at a hospital providing a Specialist ICD Service. Ultimate responsibility for implantable device therapy lies with the patient's ICD centre.

Doncaster and Bassetlaw NHS Foundation Trust does not currently provide an ICD or CRT-D Implantation or Follow-Up Service. The main ICD Centre within our region is Northern General Hospital in Sheffield.

Doncaster and Bassetlaw NHS Foundation Trust aims to provide a basic deactivation service only in order to:

- Provide an efficient deactivation service for patients admitted to the Doncaster Royal Infirmary site
- Clarify the procedure for ICD/CRT-D deactivation
- Ensure appropriate documentation of deactivation procedures

This protocol **includes** all in-patients with ICD/CRT-D who are:

- Admitted to the Doncaster Royal Infirmary site with unexpected deterioration and approaching end of life
- Admitted to the Doncaster Royal Infirmary site and covered by an active Do Not Attempt CPR Order (DNACPR)
- Admitted to the Doncaster Royal Infirmary site for routine surgery requiring diathermy/ electrocautery

- Admitted to the Doncaster Royal Infirmary site with device malfunction causing inappropriate shock therapy
- Deceased within Doncaster Royal Infirmary Mortuary

This protocol **excludes**:

- In-Patients receiving care on other sites within the Doncaster and Bassetlaw NHS Foundation Trust. In these cases, deactivation should be arranged by the patients' ICD Centre.
- Outpatients attending the Doncaster Royal Infirmary Site. Deactivation should be arranged by the patients' ICD Centre.

3. DUTIES AND RESPONSIBILITIES

Responsibility for decisions regarding Deactivation/ Reactivation of ICD/CRT-D rests with the Consultant managing the current admission in consultation with the patient and their families/carers. Where necessary, decisions should be taken after liaison with the ICD centre or Cardiologist. The Consultant (and Deputy) are therefore responsible for ensuring they are fully aware and comply with this protocol.

The lead pacing physiologist from the Cardio-respiratory Department has technical responsibility for the reprogramming of devices upon authorisation. This is undertaken with the full approval of the Consultant Cardiologist.

Due to the highly specialised nature of these devices, this service will depend on availability of specialist staff/equipment and may be adversely affected by unplanned staff absence.

Overall responsibility for implantable device therapy lies with the patients' ICD centre.

It is the responsibility of nursing staff to identify the manufacturer of implanted devices. For terminally ill patients, it is the responsibility of the ward nursing staff to ensure that a palliative care nurse specialist/ heart failure nurse specialist or member of staff known to the patient is present during deactivation to answer any patient/family concerns. Ward nursing staff have the responsibility to ensure the Mortuary is informed of the presence of an ICD/CRT-D.

Mortuary staff are responsible for arranging deactivation of ICD/CRT-D prior to removal of device for cremation.

4. PROCEDURE

4.1 Indications for Deactivation

ICD Deactivation will only be performed where there is **written authorisation** from the Consultant (or deputy) managing the current admission. Medical notes to be amended as such, ideally a written referral to the Department.

Consideration to deactivate an ICD or CRT-D should be given in the following situations:

- **Where continued use of an ICD is inconsistent with patient goals.**

- **While an active Do Not Attempt Cardiopulmonary Resuscitation order is in force.**

- **Imminent death**
  Activation inappropriate in the dying phase.

- **After death**
  Safe deactivation of ICD/CRT-D devices must be performed after death, particularly as these devices must be explanted prior to cremation.

- **During surgical procedures using diathermy/electrocautery**
  Safe deactivation of ICD/CRT-D devices may be required before surgery, particularly if diathermy/ electrocautery is to be used in close proximity to device. Diathermy can cause electrical interference which may interfere with the function of implanted devices.

- **Due to inappropriate shock therapy**
  Temporary deactivation may be considered whilst patient awaits transfer to specialist ICD centre for comprehensive device assessment.

4.2 Protocol for Deactivation - Patients approaching End of Life

Patients must have a valid Do Not Attempt CPR (DNACPR) order in place.

Consultant managing current admission (or deputy) to authorise deactivation of ICD/ CRT-D and clearly document in medical record. Where necessary, liaison with the ICD centre or consultant cardiologist may be required.

Physician requesting deactivation to complete patient consent and education (+/- discussion with relatives) prior to contacting pacing physiologists

Ward nursing staff to source manufacturer of implanted device. The device cannot be deactivated without this information:

- Each patient should carry their ICD Identification Card
- Contact ICD clinic at Sheffield Northern General Hospital or ICD Clinic at Leeds General Infirmary

Contact pacing physiologists to request deactivation/reactivation:

- Contact Cardio-respiratory Department ext 6339
- Ward nursing staff MUST state manufacturer of device

Pacing physiologist to **disable VT/VF Shock therapy and Anti-Tachycardia Pacing functions** on device and clearly document in medical record. Please note: Bradycardia pacing therapy **must** remain active.

- Programmer printout to be stored in Departmental Records within the Cardio-respiratory Department to confirm device status
- Where-ever possible, diagnostics data to be stored electronically or printed

Ideally a palliative nurse specialist, cardiac nurse specialist or a member of nursing staff known to the patient should be present during deactivation to discuss any patient/family concerns.

If the DNACPR is reviewed/reversed, Physician to request re-activation of VT/VF shock and ATP therapy. The above steps should be repeated.

4.3 Protocol for Deactivation – Patients Undergoing Surgery

Pre-Op Assessment Service to identify patients with ICD/CRT-D. Consultant anaesthetist/ consultant surgeon (or deputy) to determine whether deactivation is required. This will depend on the type of surgical procedure. Consideration should be given to the likelihood of using surgical diathermy/ electrocautery, whether diathermy is to be used in monopolar or bipolar mode, the proximity to the device and potential for interference.

Consultant anaesthetist/surgeon (or deputy) managing the surgical admission to authorise deactivation of ICD for surgery and clearly document in medical records. Liaison with the ICD centre or consultant cardiologist may be required.

Physician requesting deactivation must complete patient consent and education prior to procedure

Pre-Op Assessment Service to source manufacturer of implanted device. The device cannot be deactivated without this information:

- Each patient should carry their ICD Identification Card
- Contact ICD clinic at Sheffield Northern General Hospital or ICD Clinic at Leeds General Infirmary

Contact pacing physiologists to request deactivation/reactivation on ext 6339. This should be undertaken in advance of planned procedure date.

On date of procedure, pacing physiologist to **disable VT/VF Shock therapy and Anti-Tachycardia Pacing functions** on device and clearly document in medical record. Please note: Bradycardia pacing therapy **must** remain active.

- Programmer printout to be stored in Departmental Records within the Cardio-respiratory Department to confirm device status
- Where-ever possible, diagnostics data to be stored electronically or printed

Following completion of surgery, physician to request **Re-activation of VT/VF shock and ATP therapy** and document in ICP/medical record. The above steps should be repeated.

Bassetlaw patients with ICD/CRT-D for surgery requiring diathermy/electrocautery do not have access to this deactivation procedure and therefore require surgery to be performed at Doncaster Royal Infirmary.

4.4 Protocol for Deactivation – Patients Undergoing Endoscopy

Referring consultant/consultant in charge of patient's care to identify patients with ICD/CRT-D. Referring consultant to discuss Endoscopy procedure with relevant consultant gastroenterologist/endoscopist to determine whether deactivation is required. This will depend on the type of procedure whether it is diagnostic only or interventional. Consideration should be given to the likelihood of using surgical diathermy, whether diathermy is to be used in monopolar or bipolar mode, the proximity to the device and potential for interference.

The consultant in charge of the patient needs to authorise deactivation of ICD pre-procedure and clearly document in medical records. Liaison with the ICD centre or consultant cardiologist may be required.

The consultant requesting deactivation/consultant in charge must complete patient consent and education prior to procedure.

The referring consultant to source manufacturer of implanted device. The device cannot be deactivated without this information:

- Each patient should carry their ICD Identification Card
- Contact ICD clinic at Sheffield Northern General Hospital or ICD Clinic at Leeds General Infirmary

Contact pacing physiologists to request deactivation/reactivation on ext 6339. This should be undertaken in advance of planned procedure date.

On date of procedure, pacing physiologist to **disable VT/VF Shock therapy and Anti-Tachycardia Pacing functions** on device and clearly document in medical record. Please note: Bradycardia pacing therapy **must** remain active.

- Programmer printout to be stored in Departmental Records within the Cardio-respiratory Department to confirm device status
- Where-ever possible, diagnostics data to be stored electronically or printed

Following completion of procedure, endoscopist who undertook procedure to request **Re-activation of VT/VF shock and ATP therapy** and document in ICP/medical record. The above steps should be repeated.

Bassetlaw patients with ICD/CRT-D for surgery requiring diathermy/electrocautery do not have access to this deactivation procedure and therefore require surgery to be performed at Doncaster Royal Infirmary.

4.5 Protocol for Deactivation – Deceased Patients

Ward staff MUST inform Mortuary of the presence of an implantable cardiac device, by completing a 'Deceased Details and Mortuary Transfer Document' stating that a Defibrillator (ICD/CRT-D) is in situ.

Mortuary to confirm presence of ICD/ CRT-D

Mortuary staff to source manufacturer of implanted device where possible

- Each patient should carry their ICD Identification Card
- Contact ICD clinic at Sheffield Northern General Hospital or ICD Clinic at Leeds General Infirmary

Mortuary staff to contact pacing physiologists to request deactivation

- Contact Cardiorespiratory Department on ext 6339
- Mortuary to state manufacturer of device

Pacing physiologist to **disable VT/VF Shock therapy** and **Anti-Tachycardia Pacing functions** on device and clearly document. Please note: Bradycardia pacing therapy may also be deactivated if possible.

- Copy of programmer printout stored in Mortuary to confirm device status
- Where-ever possible, diagnostics data to be stored electronically or printed
- Where necessary, send data to ICD Centre for review
- Copies of data to be stored in Departmental Records within the Cardiorespiratory Dept

4.6 Emergencies

The pacing physiologists will provide the ICD Deactivation Service **during office hours only Monday- Friday.** Surgical cases should be listed first to ensure adequate time for re-activation.

In the event of an emergency outside these hours, a **ring magnet** (contact Sister on CCU for magnet) can be strapped over the device and will temporarily disable shock/ATP therapy in most, but not all, ICD/CRT-D. Nursing staff should position the magnet after appropriate documentation in the medical record from the consultant or deputy.

Please be aware that the magnet must be correctly and securely positioned, otherwise it will be ineffective. The device must be properly de-activated by the pacing physiologist at the earliest opportunity.

4.7 Interrogation for Diagnostic Purposes

This protocol would like to acknowledge the value of interrogating ICD/CRT-D devices to aid diagnosis. In cases where patients are admitted following ICD/CRT-D discharge, appropriately trained physiologists may interrogate the device to determine whether shock therapy was appropriate. This can aid the decision to transfer patients to the tertiary centre for comprehensive ICD/CRT-D assessment.

5. TRAINING/ SUPPORT

Cardiac physiologist/s providing this service must maintain their skills with Partner Trusts e.g. Northern General Hospital, Sheffield & Leeds General Infirmary. This is monitored through the Cardiorespiratory department.

Manufacturing companies provide support with training courses when required/available and for device related advice.

6. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
The service will be reviewed when new national or international guidance are received	Pacing/ICD Service Lead, Cardio-Respiratory Department Clinical Governance	Bi-monthly	Reported to Cardiology Clinical Governance, Speciality Services Care Group
When newly published evidence demonstrates the need to change current practice	Pacing/ICD Service Lead, Cardio-Respiratory Department Clinical Governance	Bi-monthly	Reported to Cardiology Clinical Governance, Speciality Services Care Group

7. DEFINITIONS & ABBREVIATIONS

ICD	Implantable Cardioverter Defibrillator
CRT-D	Cardiac Resynchronisation Therapy device with Defibrillation Function
DNACPR	Do Not Attempt Cardiopulmonary Resuscitation Order
VT	Ventricular Tachycardia
VF	Ventricular Fibrillation
ATP	Anti-Tachycardia Pacing
ICP	Integrated Care Pathway
CCU	Coronary Care Unit
CXR	Chest X-Ray

8. EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. ElA included, see Appendix 3.

9. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

PAT/EC 2 – Do Not Attempt Cardiopulmonary resuscitation (DNACPR) policy.

PAT/T 60 – Death of a patient – Operational Policy for staff to follow in the event of a patient death.

10. REFERENCES

This protocol was developed following a review of the following documents and guidelines:

Arrhythmia Alliance (2010), Implantable Cardioverter Defibrillators (ICDs) in Dying patients. Leaflet, January 2009 reviewed April 2010. Available at: http://www.heartrhythmcharity.org.uk/www/media/files/For_Patients/100413-FINAL-ICD_in_Dying_Patients.pdf

British Heart Foundation (2013). ICD deactivation at the end of life: Principles and practice. A discussion document for healthcare professionals. Available at: http://www.bhf.org.uk/plugins/PublicationsSearchResults/DownloadFile.aspx?docid=6d41b3de-30ae-425b-a4a3-e52e75be2a5c&version=-1&title=ICD+deactivation+at+the+end+of+life%3a+Principles+and+practice&resource=M106

England R, England T, Coggon J (2007). The ethical and legal implications of deactivating an implantable cardioverter-defibrillator in a patient with terminal cancer. Journal of Medical Ethics. 2007; 33:538-540. Available at: jme.bmj.com/cgi/content/full/33/9/538

Epstein AE, Dimarco JP, Ellenbogen KA, Estes M, Freedman RA (2008). ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons. **Circulation**; 117; p350-p408; originally published online May 15, 2008.

Heart Rhythm UK (January 2013), Standards for Implementation and follow-up Cardiac Rhythm Management Devices in adults, Available at: http://www.heartrhythmuk.org.uk/files/file/Docs/Position%20Statements/121214-1-Heart%20Rhythm%20UK%20standards%20for%20CRM%20devices%20in%20adults%202013.pdf

Lampert R (2012). Death Does Not Have to Be a Shocking Experience: Deactivation of Cardiac Rhythm Devices at Patients' End of Life http://crm.cardiosource.org/Learn-from-the-Experts/2012/08/Deactivation-of-Cardiac-Rhythm-Devices-at-Patients-End-of-Life.aspx

Medical and Healthcare products Regulatory Agency. Guidelines for the peri-operative management of patients with implantable pacemakers or implantable cardioverter defibrillators, where the use of surgical diathermy/electrocautery is anticipated. March 2006. Available at: http://www.mhra.gov.uk/home/groups/dts-bi/documents/websiteresources/con2023451.pdf

APPENDIX 1 - CONTACT DETAILS – DEVICE MANUFACTURER

Contact Details - Device Manufacturer

Manufacturer	**Address**	**Contact Details**
Biotronik	Biotronik UK Ltd Biotronik House Avonbury Business Park Bicester OX26 2UA	Tel: 01869 362100 Fax: 01869 362101 Mob: 07850 407940 ***24 hour Helpline*** ***0800 1951030***
Boston Scientific (previously Guidant)	Boston Scientific Limited Breakspear Park Breakspear Way Hemel Hempstead Herts HP2 4TZ	Tel: 0844 800 4515 Fax: 0844 8004516 European Technical Service +3224167222 (24hr helpline)
Cameron Health (an acquired company of Boston Scientific)	Boston Scientific Limited Breakspear Park Breakspear Way Hemel Hempstead Herts HP2 4TZ	Tel: 0844 800 4515 Fax: 0844 8004516 European Technical Service +3224167222 (24hr helpline)
Medtronic/ Vitatron	Medtronic Ltd Suite One Sherbourne House Croxley Business Centre Watford Herts WD18 8WW	Tel: 01923 212213 Fax: 01923 241004 ***Directo 24hour Helpline*** ***08702 403304***

Sorin Group (ELA Medical)	Sorin Group UK 1370 Montpellier Court Gloucester Business Park Hucclecote Gloucester GL3 4AH	Tel: 01452 638500 Fax: 01452 638530 ***24hour Helpline*** ***0870 2385460***
St. Jude Medical	St. Jude Medical UK Ltd Capulet House Stratford Business and Technology Park Banbury Road Stratford-upon-Avon CV37 7GX	Tel: 01789 207600 Fax: 01789 207601 Lifeline 24hour helpline ***07808 910454***

APPENDIX 2 – CONTACT DETAILS - STAKEHOLDERS

Department	Location	Details
Cardio-respiratory Department,	South Block, Doncaster Royal Infirmary	Vivienne Hayward (lead pacing physiologist) Tel: 01302 381339 vivienne.hayward@dbh.nhs.uk
Cardiology	Doncaster Royal Infirmary	Clinical Director/Consultant Tel: 01302 366666 ext 4073 Pager: 07659 529564
Coronary Care Unit,	Doncaster Royal Infirmary	Sister Tel: 01302 366666 ext 3355
Endoscopy,	Doncaster Royal Infirmary	Senior Sister Endoscopy Tel: 01302 366666 ext 472
Resuscitation Department	Doncaster Royal Infirmary	Technical Instructor Tel: 01302 366666 ext 6119
Pre-Op Theatre Assessment	Doncaster Royal Infirmary	Specialist Nurse Practitioner Tel: 01302 366666 ext 6394
Mortuary	Doncaster Royal Infirmary	Technician Tel: 01302 366666 ext 3526
Pre-Op Orthopaedic theatre Assessment	Doncaster Royal Infirmary	Specialist Nurse Practitioner Tel: 01302 366666 ext 4185
Macmillan Palliative Nurse Specialist	Doncaster Royal Infirmary	Macmillan Palliative Nurse Specialist Tel: 01302 366666 ext 3142

APPENDIX 3 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/ Project/Strategy	CSU/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Procedure for Deactivation for ICD and CRT devices	Clinical Specialities, Cardiorespiratory Department	Vivienne Hayward	Existing Service/Policy	09/10/2014

1) Who is responsible for this policy? Name of CSU/Directorate Cardiorespiratory Department, DRI

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes?
Benefit: Inpatients requiring deactivation of these devices or interrogation of devices to check whether they have had appropriate/inappropriate shocks,
Theatre & Endoscopy patients who require these devices deactivating prior to the procedure,
Mortuary personnel where these devices need deactivating prior to removal from the body.
Intended outcome: To provide an efficient deactivation service for patients admitted to DRI

3) Are there any associated objectives? Legislation, targets national expectation, standards
MHRA medical device alert 22/09/2008 – MDA/2008/068 Implantable cardioverter defibrillators
MHRA (March 2006) Guidelines for Perioperative management of patients with implantable pacemakers or implantable cardioverter defibrillators, where the use of surgical diathermy/electrocautery is anticipated
BHF – Implantable cardioverter defibrillators in patients who are reaching the end of life

4) What factors contribute or detract from achieving intended outcomes? –
Contribute: Specific trained staff, in-house facilities (reprogrammers)
Detract: Staffing levels

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] –
Positive impact on patients with ICD & CRT-D devices (These patients cover a broad spectrum of ages, gender & race

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? [any actions to be taken]

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	no	
b) Disability	no	
c) Gender	no	
d) Gender Reassignment	no	

e) Marriage/Civil Partnership	no	
f) Maternity/Pregnancy	no	
g) Race	no	
h) Religion/Belief	no	
i) Sexual Orientation	no	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick outcome box

Outcome 1✓	**Outcome 2**	**Outcome 3**	**Outcome 4**

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4

Date for next review: 01/09/2017

Checked by: Vivienne Hayward **Date: 17/09/2014**