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The Royal College of Radiologists

Radiotherapy Board

Guidance on the management of patients with cardiac implantable electronic devices receiving radiotherapy

January 2025

Produced in association with:

British Cardio-Oncology Society

BRITISH CARDIO ONCOLOGY SOCIETY www.BC-OS.org

British Heart Rhythm Society

BHRS British Heart Rhythm Society

Contents

Foreword

The Radiotherapy Board is a partnership between the Institute of Physics and Engineering in Medicine, the Society and College of Radiographers and The Royal College of Radiologists. It provides guidance, oversight and support for the continuing development of high-quality radiotherapy services for cancer patients in the UK.

In 2015 the Radiotherapy Board published *Management of cancer patients receiving radiotherapy with a cardiac implanted electronic device: A clinical guideline.* Since that time, the use of cardiac devices has increased and there have also been changes in clinical practice affecting how patients with such devices should be managed. The Radiotherapy Board therefore commissioned a multi-professional Working Group to review and update the original guidelines and produce this new edition.

The purpose of this guidance is to recommend the best evidence-based practice for managing patients with a cardiac implantable electronic device (CIED) who require radiotherapy. The guidance:

- distills recently published guidelines to aid decision-making when patients with CIEDs are referred for radiotherapy
- covers all steps in the treatment process, from referral through pre-treatment imaging and planning to pre-treatment checks, Imaging Guided Radiotherapy treatment and treatment delivery
- provides pragmatic guidelines for the assessment of risk with appropriate safety measures, including advice on risk mitigation, risk category management and documentation.

The Working Group comprised representatives from Clinical Oncology, Radiotherapy Physics and Therapeutic Radiography, with input also from cardiology by members of the British Cardio-Oncology Society (BC-OS) and the British Heart Rhythm Society (BHRS). The Radiotherapy Board would like to thank all members of the Working Group for their hard work, dedication and commitment to developing this new guidance (see Acknowledgements) and in particular Karen Smith, Stefano Sirianni and Nick West for their leadership of this new edition. The Radiotherapy Board would also like to thank the BC-OS and the BHRS for their input.

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Executive Summary: The Radiotherapy Pathway

Outpatient Clinic

- Ensure an appropriately trained practitioner has had a risk-benefit discussion with the patient regarding possible device malfunction and management during radiotherapy. This discussion should be annotated on the IR(ME)R17 referral and documented on the consent form.
- Contact the patient's device clinic to:
  - Ensure the CIED is under regular follow-up and request a report of the last device check and documentation of all programmed parameters
  - Check if there is a history of ventricular arrhythmia or ICD therapy and CIED pacing dependency (VVI, <30 beats/min, see Appendix C for full description).

Pre-treatment

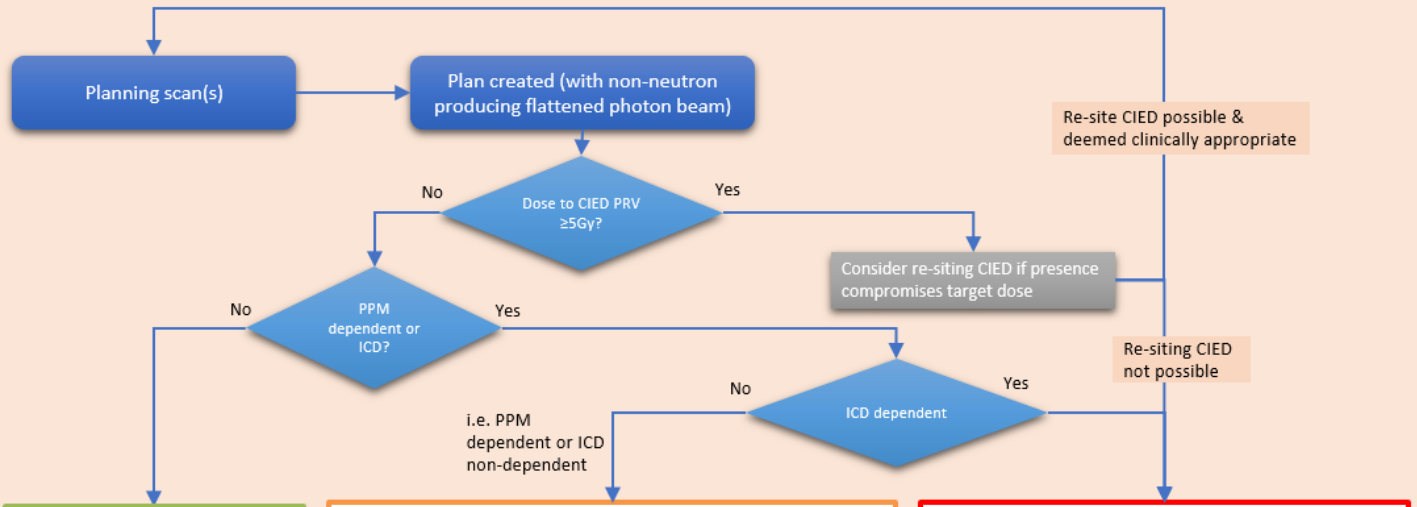
- The pre-treatment radiographers should ask all patients if they have a CIED prior to CT scanning
- Avoid direct CT irradiation when possible. However, the extent of the CT scan should not be compromised if needed for OAR delineation or to estimate CIED dose if potentially ≥5Gy

CT helical scans (pitch >1) are preferred to prevent long periods of direct irradiation[11]. See paragraph 3.1 for details on axial scanning.
For magnetic resonance (MR) simulators, CIED compatibility must be verified before simulating the patient.

Planning

- Determine if the patient has had prior irradiation within close proximity to the device
- Avoid direct irradiation to minimise dose to CIED PRV (PRV margin dependent on technique, immobilisation and IGRT)
- Avoid neutron-producing beams (photons ≥10MV, protons, heavy ions), high dose rate beams (FFF) and high energy electron beams (≥20MeV)

For non-neutron producing, flattened photon beams



LOW RISK

Close monitoring of the CIED patient with audio-visual system during treatment by therapeutic radiographers. Pacemaker magnet, pulse oximetry and AED must be available in the vicinity.

CIED check at the START (within 6-12 months) and END of treatment.

MEDIUM RISK

As per Low-Risk **AND**:

PPM Pacing Dependent: Appropriately trained staff (i) Place a magnet over the PPM during radiotherapy OR have the device reprogrammed to a non-sensing mode during each session. (ii) Continuous cardiac monitoring using 3-lead ECG during every fraction.

ICD non-pacing dependent: Appropriately trained staff (i) Place a magnet over device to temporarily inhibit tachycardia therapy (bradycardia pacing is unaffected). (ii) Continuous cardiac monitoring using 3-lead ECG during every fraction.

CIED check at START (<12 months), MID-TREATMENT, END of treatment and at 6 months.

HIGH RISK

As per Medium-Risk **AND**:

ICD pacing dependent: Appropriately trained staff (i) Reprogram BEFORE and AFTER each radiotherapy fraction. (ii) Place a magnet over to temporarily inhibit tachycardia therapy.

Continuous cardiac monitoring during every fraction.

CIED check at START, WEEKLY once the device receives >5 Gy, END of treatment and at 6 months.

For details regarding appropriately trained staff see sections 5.4 Monitoring Process and 6. Non-Medical Healthcare Professionals Led Monitoring: Training and Competencies

Emergency Palliative treatment (dose and CIED information not available)

- Use continuous cardiac monitoring where available
- Refer the patient to their pacing clinic for a device check within 2 weeks of treatment delivery.
- Keep doses <2Gy. If dose is not calculated, departments should generate rules (that will be device, immobilisation and IGRT technique dependent) to inform the safe distance from field edge to device.

1. Background

1.1. Epidemiology

There are 3 million people living with cancer in the UK[3,4,5,6]. It is predicted that this number will rise to 5.3 million by 2040. The proportion of patients who receive radiotherapy at some stage of their illness is around 50 per cent[7]. The number of patients with a CIED is also increasing. Recent reports estimate around 400 patients per million per year might be suitable for cardiac resynchronisation therapy[26]. As a result, radiotherapy clinics will continue to see more patients with a CIED.

1.2. Published guidelines

For a tabulated summary of guidance from 2012 onwards on the management for CIEDs during radiotherapy, see Appendix A.

1.3 Radiotherapy with kilovoltage X-ray and brachytherapy

Radiotherapy in the kilovoltage (kV) energy range (50-500kV) includes superficial/orthovoltage therapy and brachytherapy-delivered isotopes or electronic brachytherapy isotopes. These are not neutron-producing[8] and delivery mechanisms will pose very little risk of electromagnetic interference to CIEDs[9].

1.3.1 Superficial / Orthovoltage (kV) X-rays

This modality uses X-ray tubes to deliver radiation in the energy range 50-500 kV. It is often used for superficial tumours (eg. skin cancer).

kV treatments, typically utilising skin contact applicators, have sharp penumbrae, resulting in rapid dose fall-off outside the field edge. Through selection of appropriate beam angles, direct irradiation of the CIED can be avoided, minimising dose and therefore risk. Risk must be assessed for each patient since it is dependent on prescription and plan geometry.

1.3.2 Brachytherapy

Brachytherapy is a method of delivering radiation to treat localised disease with relatively small volumes that are easily accessible.

Isotope Brachytherapy

Isotopic sources containing Iridium-192 are commonly used for brachytherapy. These are positioned in or close to the target volume, often making use of natural body cavities, with the advantage that patient and organ movement does not generally change the dose distribution.

As with superficial x-rays, for simple treatments it is possible to define a set of conditions which pose a low risk to a CIED because of the low dose (<5 Gy) to which it is exposed. Centres may want to establish conditions in which low and high-risk scenarios occur since they are dependent on source energy, activity, prescription and plan geometry. For more complex arrangements, users can estimate dose to the CIED using the brachytherapy treatment planning system. Centres should seek to confirm such scenarios and treatment planning system calculations with measurements to establish generalised conditions, or alternatively make measurements for individual situations.

Electronic Brachytherapy

Electronic brachytherapy uses kV X-rays generated by a small device either within or on the surface of the patient. It is typically used for intra-operative tumour bed irradiation as an alternative to external beam radiotherapy and operated at ~40-50 kV. Doses exhibit very rapid fall-off in tissue because of the low energy spectrum.

Intraoperative radiotherapy has been recognised as advantageous for targets close to CIEDs[18]. This is due to the significant attenuation of the radiation produced and its operation with minimal electromagnetic interference. The advice for electronic brachytherapy is similar to that given above for isotope brachytherapy: centres will need to determine a distance at which the dose to the CIED falls to a safe level or have methods to estimate doses to the CIED.

Risk to patients with a CIED undergoing kV radiotherapy treatments

For patients with a CIED undergoing radiotherapy in the kV range, risk may be stratified with dose in a similar way to those having megavoltage X-ray treatment.

1.4. Proton / heavy ions beams

Proton and heavy ion beams produce secondary neutrons and may themselves directly induce CIED faults[10]. It is therefore recommended to treat them as high-risk category.

1.5. Cardiac Implantable Electronic Devices (Appendix B: List of operating manuals provided by manufacturers)

Permanent Pacemaker (PPM) - implanted to treat slow heart rhythms (bradycardia). These devices are programmed to promote intrinsic cardiac conduction, therefore only pace when the heart rate falls below the appropriate pre-specified level.

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 only pace the heart if the heart rate is less than the appropriate pre-specified level.

Cardiac resynchronisation therapy (CRT) - implanted to treat patients with left ventricular systolic dysfunction and bundle branch block. These devices work by coordinating ventricular contraction and as such are programmed to pace the heart continuously. These devices can just work as a pacemaker (CRT-P) and should be treated as PPM for the purpose of the guidance, or can be combined as an ICD (CRT-D) and for the purpose of these guidelines the ICD guidance should be followed.

Subcutaneous Implanted Cardiac Defibrillator (S-ICD) - similar to an ICD but with the advantage of an absence of leads within the heart and the preservation of central venous circulation.

Leadless Pacemaker - similar to a PPM but with the advantage that the pacemaker is directly implanted into the heart without the use of leads. As pacemakers, particularly leadless, become smaller and more discrete, extra vigilance will be required to identify devices prior to radiotherapy planning and delivery; basic pacemaker parameters should be requested from the patient's cardiology centre. Good communication and relationship with the cardiology team will assist in keeping abreast of pacemaker developments and identifying new CIED designs. This guidance recommends managing leadless pacemakers in the same way as PPM. The cardiology team should assist the radiotherapy department to re-programme the device if necessary.

1.6. Effects of radiotherapy on CIED: mode and clinical consequences of failure

While diagnostic ionising radiation rarely interferes with CIEDs, therapeutic radiation (RT) can have several potential undesirable effects on device function, especially when the energy produced by the Linear Accelerator (linac) is particularly high or the beam irradiates the generator directly.

CIED malfunctions occur at a rate that is sufficient to pose a challenge to radiotherapy. When devices fail during radiotherapy, malfunctions manifest primarily as software impairments, possibly leading to a reset of the device. There have also been reports of interference leading to battery depletion, oversensing and delivery of inappropriate shock therapy in ICDs[11]. Manufacturers' recommendations vary greatly (see Appendix B) and can be at odds with peer-reviewed publications.

According to recently published evidence (see Appendix A), risks are associated with:

Cumulative dose: Error thresholds ranging from 0.1 to 10 Gy

Neutrons: Photons ≥10MV, Electrons ≥20MeV, protons and heavy ions (all clinical energies) being associated with neutron production

High dose-rates: ≥ 8 Gy/minute have a high risk of device malfunction whilst < 0.2 Gy/minute demonstrate a very low chance of malfunction

Electromagnetic interference (EMI) EMI from MR scanners could trigger unwanted CIED side-effects although EMI around modern linear accelerators is negligible.

The impact of radiotherapy on CIEDs can be temporary or permanent. The following table summarises the clinical consequences of different modes of CIED failure:

CIED Failure	Potential Device Malfunction	Pacemaker	ICD
Complete CIED failure	No pacing or shock function	✓	✓
Reversion to safety mode	Limited, unreliable pacing	✓	✓
Accelerated battery depletion	Urgent box change required	✓	✓
Reduced pacing outputs	No pacing	✓	✓
Reduced shock energy	Unsuccessful shocks		✓
Oversensing of interference	No pacing	✓	✓
Oversensing of interference	Inappropriate shocks		✓
Loss of remote communication	Unable to program CIED	✓	✓

1.7. Electromagnetic Interference

Electromagnetic Interference (EMI) arising from radiotherapy equipment is subject to international standards governing the emission of - and immunity to - EM radiation. The two main UK linac manufacturers issue manuals containing details of the standards and levels to which their equipment complies. These include IEC60601-1-2, CISPR 11 and EN55011:2009. As a result, the levels of EMI around modern linacs are low and consequently there have been no reported EMI-induced malfunctions since 1990[9].

2. The Radiotherapy Process (What, Who, How)

It is recommended that each centre has a designated lead for managing patients with CIEDs undergoing radiotherapy and that all such patients are discussed with the appropriate Multi-Disciplinary Team, to ensure consistency of advice, management, treatment and monitoring.

2.1. Radiotherapy Referral

It is imperative to identify patients with CIEDs as early as possible within the radiotherapy pathway.

At referral:

- **Confirm** whether the patient has a CIED and type
- **Identify** the patient's cardiology care provider to obtain information on the device and determine pacing dependency (see Appendix C: Cardiac Pacing Dependency)
- **Consent** the patient and inform them that the CIED may be adversely affected by the radiotherapy treatment, including the implications and risks of malfunction
- **Ensure** that the correct process is followed in out-of-hours and emergency situations (see Appendix E).

Clinicians should be aware that:

Category 1 patients whose treatment may be delivered outside standard hours should be individually risk-assessed based on the required precautions specific to the heart - eg. when there are no appropriately trained staff to provide monitoring, consider deferring treatment with compensation for missed fractions.

2.2. Preliminary Treatment Considerations

Ensure that the CIED is NOT directly in the high dose volume. If this is unachievable, different treatment techniques (eg. partial breast vs whole breast irradiation) or machine-specific modalities must be considered and assessed on an individual basis following consultation with the patient, their cardiologist and a Medical Physics Expert. However:

- ***The quality of the treatment plan should not be significantly compromised for the sake of sparing the device.***

Consideration should be given to repositioning the device while leads are left in place, particularly if the patient has a low cardiac output and is pacing dependent. The 2017 HRS consensus report states explicitly that moving the device is inappropriate if the device receives less than 5 Gy^2 (see Appendix C: Device Relocation).

3. Pre-Treatment Process: scan imaging modalities

Pre-treatment radiographers or mould room technicians should:

- Ask all patients if they have a CIED prior to scanning and what type
- Check that the patient's consent form includes reference to potential adverse effects on the CIED function*.

**** Discuss with the referring clinician if CIED status has not been documented on referral or consent.***

3.1. CT scan

Computed tomography (CT) scans will irradiate devices with a direct beam for a very short period of time and consequently pose a low risk, with no clinically significant malfunctions having been reported. Changes in device parameters have been reported but these were deemed unlikely to lead to adverse clinical events, although a definitive link to CT scan was not confirmed[1]. For prolonged scans, such as 4DCTs (axial scans), that might directly irradiate the device for longer than 3 seconds, a small theoretical risk of malfunction exists. However, in these situations there is very little evidence of failures for modern devices[11].

Nevertheless, dose to CIEDs should be minimised whenever possible:

- If a device is more than 10cm from a potential field edge it is not necessary to include in the planning CT scan (radiotherapy dose will be <2Gy). Scan extent should not be compromised if required for target and organs at risk (OAR) delineation.

The presence of a CIED may introduce errors in the CT reconstruction, appearing as artefacts on the resulting CT scans and degrading the quality of images. Implant-generated artefacts may potentially reduce the visibility of targets and organs at risk in the immediate vicinity of the device. These can be minimised through the appropriate selection of CT protocols and application of commercial image-processing algorithms offering metal artefact reduction (MAR).

3.2 MRI scan and Linac

Prior to Magnetic Resonance (MR) scanning at both pre-treatment and delivery with MR linacs, CIED compatibility must be verified with a device clinic or manufacturer. The Joint British Society consensus recommendations for MR imaging for patients with CIEDs[27] discuss how to perform MR scans for patients with cardiac devices. Refer to local Standard Operating Procedures for requirements regarding reprogramming devices to MR mode and monitoring alongside manufacturers conditions for monitoring. The effects of MR imaging are explained in detail in the HRS 2017 consensus report[2] and on the BHRS website[28].

4. Treatment planning

This is the process by which the arrangement of radiation beams is made, optimising their size, energy and intensity, along with modality, dose and fractionation for the specific clinical situation. The radiotherapy treatment is designed to conform high doses to the target and minimise dose to OAR. Planning recommendations include:

- **Use energies <10MV** to minimise neutron production. If energies at 10MV and above cannot be avoided, then the patient must be managed within the high-risk category.
- **Avoid heavy ions and protons** if possible. If necessary, then manage the patient in the high-risk category.
- **High dose rates should be avoided**. Use flattened beams where possible to reduce dose rates.

4.1 Plan Geometry

There can be some flexibility, particularly in the beam arrangement, which means that the dose to a CIED can be minimised. These include:

- Avoid direct irradiation of the CIED in the linac treatment field - including the exit beam - by selecting beam angles and arcs to maintain target coverage while minimising dose to the device.
- When using intensity modulated radiotherapy (IMRT), use dose constraints and protect/avoid functionality in the Treatment Planning System (TPS) to limit the CIED dose even when in the main beam.
- Planning protocols and checklists can be employed to ensure the above measures are used where appropriate.

4.2 Dose Reporting

- If the CIED is visible on the CT and within 10cm (superiorly or inferiorly) of treatment field edges, then it should be outlined and a technique-appropriate Planning Risk Volume (PRV) margin applied (CIED PRV).
- Near maximum estimates of dose (using an appropriately small volume - eg. 0.035cc) to the CIED PRV should be recorded.
- Recommended near-maximum dose (eg. D0.035cc) to CIED PRV is <5Gy.
- If the CIED is >10cm superiorly or inferiorly from the edge of the treatment beam, it can be assumed that the near-maximum dose (eg. D0.035cc) to the CIED PRV will be <2Gy.

> The dose estimate should be the cumulative dose and include dose contributions from previous radiotherapy treatment and on-treatment verification imaging. If the device is within the cone beam CT field of view then the dose can be approximated to 0.01Gy per scan (dose to water), although in some cases it might be possible for the scan limits to be adjusted to exclude the device.

4.3 When to seek further advice

If meeting CIED dose constraints compromises target coverage then the clinician should discuss this with the patient's pacing clinic to obtain the make and model of the pacemaker or ICD, the manufacturer quoted tolerance and any specific information relating to the device and the potential risk to the patient due to device failure.

If the quoted manufacturer tolerance is likely to be exceeded, the clinician should be informed immediately and other options discussed as sometimes it is possible to move the CIED to another location before treatment (see Appendix F).

5. Treatment Delivery

5.1 Pre-treatment checks

The pre-treatment team must ensure that:

- All documentation (dose estimates, CIED evaluation report, consent) are present and any actions are undertaken prior to the commencement of radiotherapy treatment.
- A cardiac arrest trolley equipped with an automated external defibrillator (AED) capable of delivering external pacing is available within the department and staff are adequately trained to use the equipment.
- Appropriate arrangements have been established with appropriately-trained professionals if on-treatment monitoring is required.

5.2 Risk Category and Management

Patients' pacing dependency mainly determines the impact of the CIED failure on the patient, whereas the cumulative dose and the presence of contaminating neutrons, protons or heavy ions are associated with risk of device malfunction[9,10]. These aspects are combined to stratify patients' categorisation as low, medium and high-risk (Figure 1).

5.3 Management of Rate Adaptive Devices

Care should be taken during monitoring as rate adaptive devices could be triggered by radiofrequency (RF) / EMI generated by treatment units which could induce paced tachycardia. This should be discussed with the patient prior to delivery of the first fraction and annotated on the CIED form.

Devices with dual chamber settings and rate adaptive devices which are not enabled can switch mode into 'rate adaptive enabled' setting if atrial fibrillation occurs. Once sinus rhythm is restored the pacemaker should revert quickly to the normal atrial tracking mode. If a transient rate increase is observed during radiotherapy the patient should be informed and the referring cardiology department should be contacted.

In the event of emergency radiotherapy where rate adaptive status is unknown, treatment should be interrupted if tachycardia occurs until normal rhythm is resumed. If the patient is haemodynamically stable and a tachycardia stops when therapy stops then this is likely to be a transient EMI/RF effect as the CIED programming should not allow significant arrhythmia to be sustained.

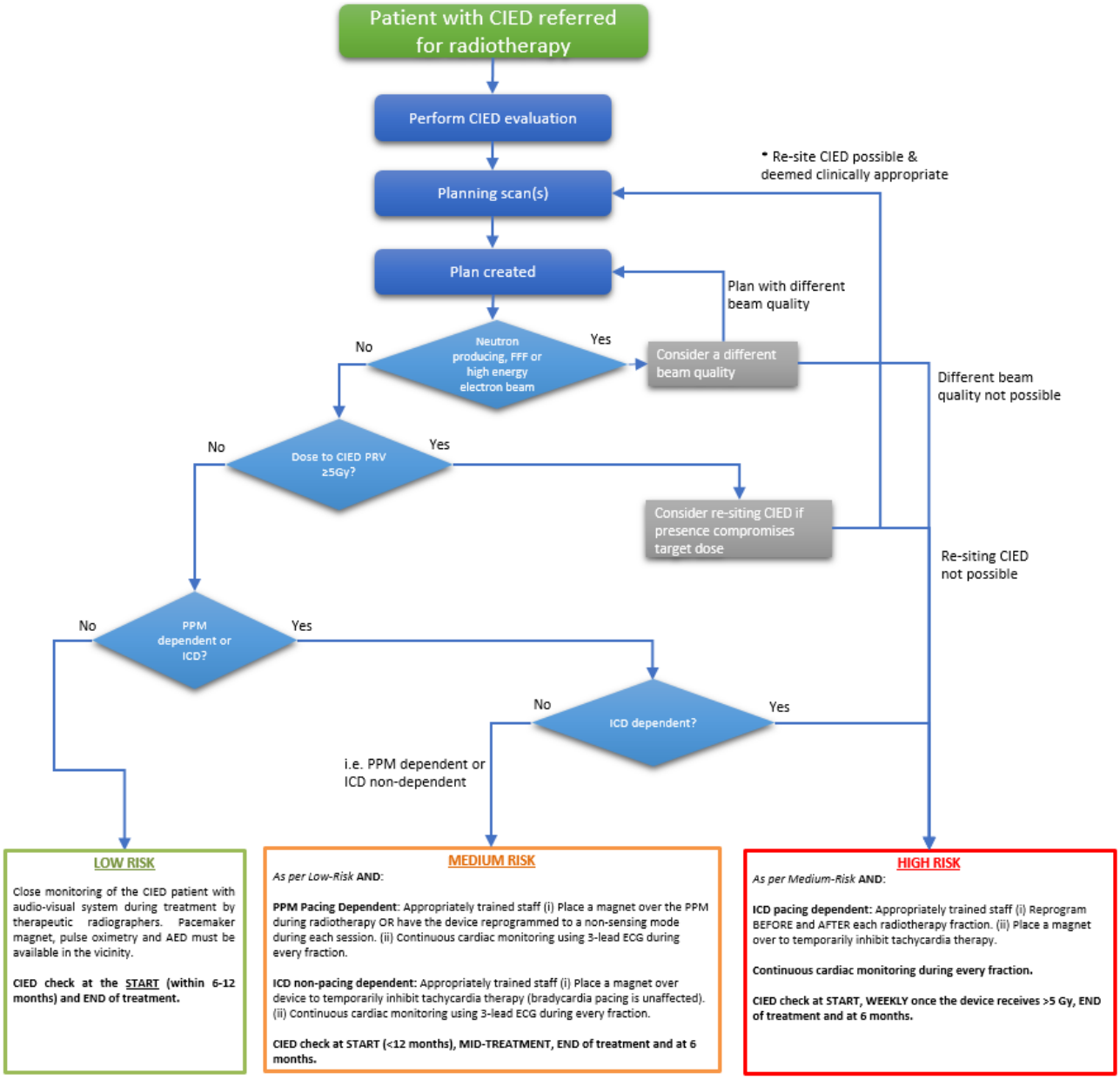


Figure 1: Workflow for the management of patients referred for external beam radiotherapy and identified as having a CIED.

**Relocation is not recommended when the maximum dose to the CIED PRV is <5Gy[2].*

5.4 Monitoring Process

The goal of continuous cardiac monitoring with electrocardiogram (ECG) during radiotherapy is to aid immediate recognition of device malfunction that may lead to life-threatening arrhythmia.

There is a lack of data on the benefit of continuous cardiac monitoring during radiotherapy[2], but it is strongly recommended to use cardiac monitoring for patients who are pacing dependent, those whose device battery is nearing end of life or those with ICDs[24].

Staff who deploy the monitor should have basic training in arrhythmia recognition, especially bradycardia and tachycardia (see Chapter 6)**; minimum Immediate Life Support (ILS) training.**

Ideally the cardiac monitoring system should have the following as a minimum:

- 3-lead ECG
- An alarm system with both audible and visual alerts
- AED capable of delivering external pacing
- A display that can be visualised from outside the treatment room
- A system for either printing or uploading ECG data to an electronic health record.

5.4.1 On first day of treatment

An appropriately-trained member of staff (*in addition* to the treatment team) must assess and monitor the patient using the cardiac monitor, advising on when to switch the beam on and, if necessary, switch the beam off.

5.4.2 During subsequent treatments

- Ensure a cardiac physiologist will interrogate the device at the middle of the treatment course (if required) or weekly once the device has received >5Gy.
- The patient must have their CIED checked at their referring hospital within 2 weeks of completing treatment.
- The patient must receive an advice letter and cardiology follow-up instructions by the last day of treatment.

5.5 Malfunction detection and the deteriorating patient

5.5.1 Malfunction of pacemaker

If a patient with a pacemaker is haemodynamically unstable, initiate resuscitation and call the cardiac arrest team, seeking urgent cardiology advice following resuscitation.

5.5.2 Malfunction of ICD

If the patient receives an appropriate therapy for a ventricular arrhythmia, further action need not be taken, other than to be sure that the patient is clinically stable. The CIED must be interrogated prior to patient discharge.

If an ICD appears to be delivering shocks inappropriately, a magnet positioned over the device will stop the delivery of shocks and anti-tachycardia therapy but will not affect the pacemaker function of the ICD. Urgent advice from a cardiologist should be sought. If the patient appears tachycardic and haemodynamically unstable, the magnet should be removed to allow restoration of ICD therapy and treat the unstable ventricular arrhythmia that may be occurring.

All unexpected CIED events detected during the radiotherapy course and in the follow-up period must be systematically recorded using the centre's incident reporting system and explained to the patient.

6. Non-Medical Healthcare Professionals-led Monitoring: training and competencies

To overcome issues in monitoring and managing patients with CIEDs arising from lack of medical cover and absence of cardiology support, this guidance recommends implementing a service led by designated non-medical healthcare professionals and support staff. The training could be completed by various members of the multi-disciplinary team (MDT) such as therapeutic radiographers, nurses, medical physicists and healthcare assistants where this is in line with existing scopes of practice.

Ongoing training and/or refresher training is necessary to ensure designated staff maintain competency. This is especially important in light of the anticipated low numbers of patients with CIEDs that will require monitoring.

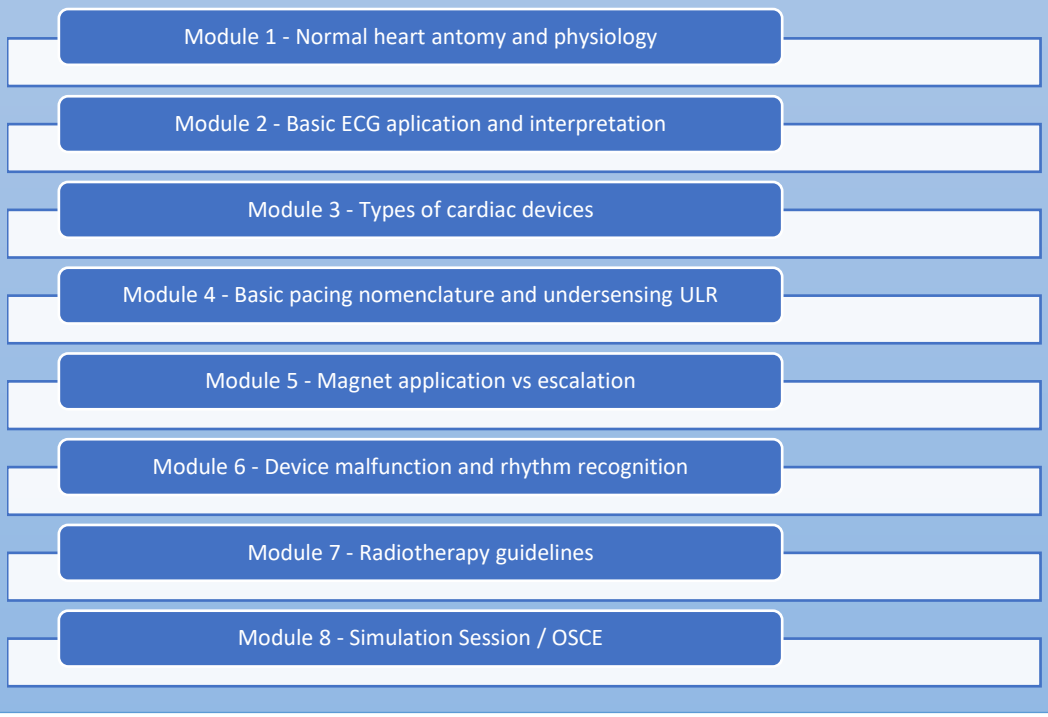
Below is an example of a training package developed at Barts Health NHS Trust, London, UK. Radiotherapy centres can develop their own training package in conjunction with their local cardiology service.

Example of Non-Medical Healthcare Professional led monitoring training package (Barts Health NHS Trust, London, UK 2016)

The training consists of:

- Cardiac theory workbook
- ILS Training and Assessment
- 2 days cardiac and ECG analysis training lectures with exam
- Collection of patient specific competencies/or OSCE under observation

Topics covered:



7. Towards Evidence-Based Guidance

Whilst relatively few adverse events for patients with CIEDs undergoing radiotherapy have been reported in the literature, guidance must reflect the potential for significant adverse effects in the device and proceed cautiously. However, there is an increasing cohort of non-clinical, *in vitro* studies suggesting that modern CIEDs may be more resilient to high energy radiation than previously thought.

There does, however, remain a paucity of clinical reports detailing the safe delivery of radiotherapy and whilst this guidance recommends implementing a conservative approach to delivering radiotherapy to patients with CIEDs, guidance must evolve to ensure we focus resources appropriately. It is therefore strongly encouraged that centres publish cases where devices receive a non-trivial radiation exposure along with detailed reports of device behaviour before, during and after the radiotherapy course.

8. Abbreviations

AED	Automated external defibrillator
BHRS	British Heart Rhythm Society
CBCT	Cone Beam Computed Tomography
CIED	Cardiac Implantable Electronic Device
CRT	Cardiac Resynchronisation Therapy
CRT-D	Cardiac Resynchronisation Therapy with implantable cardioverter-defibrillator
CRT-P	Cardiac resynchronisation therapy with pacemaker
CT	Computed Tomography
ECG	Electrocardiogram
EMI	Electromagnetic Interference
FFF	Flattening Filter Free
Gy	Gray
ICD	Implanted Cardioverter Defibrillator
ILS	Intermediate Life Support
IR(ME)R17	Ionising Radiation Medical Exposure Regulations 2017
IMRT	Intensity Modulated Radiotherapy
kV	Kilovoltage
Linac	Linear accelerator
MDT	Multi-Disciplinary Team
MRI	Magnetic Resonance Imaging
MV	Megavoltage
OAR	Organ at Risk
PPM	Pacemaker
PRV	Planning Risk Volume
PTV	Planning Target Volume
RF	Radiofrequency
RT	Radiotherapy
SABR	Stereotactic Ablative Body Radiotherapy
S-ICD	Subcutaneous Implanted Cardiac Defibrillator
TPS	Treatment Planning System
VMAT	Volumetric Modulated Arc Therapy
VVI	Asynchronous ventricular inhibited stimulation

9. Acknowledgements

This guidance has been prepared by a multi-professional Working Group:

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Appendix A: Summary of National Guidelines from 2012 onwards

		Low Risk	Medium Risk	High Risk
Comparison of risk classification	**JASTRO/JCS**[1] • *When using an FFF beam, consider raising the risk by one step according to the patient's condition.* • *For brachytherapy, manage as a photon beam and risk classification is based on other requirements.*	• Photon <10 MV • or electron <20 MeV • Not PM-dependent • No irradiation of the chest • Device dose <2 Gy • No history of ventricular tachycardia	• Other than low and high risk	A patient with any of the following is classified at high risk: • Photon ≥10 MV • Electron ≥20 MeV • Proton beam • Carbon-ion beam • PM-dependent • CIED dose >10 Gy • History of ventricular fibrillation • History of ICD intervention
	AIAC/AIRO/AIFM[19]	PM • Photons or electrons ≤6 MV • Dose to CIED ≤2 Gy, • Not PM-dependent ICD • Photons or electrons ≤6 MV • Not PM-dependent, • No frequent ICD interventions • Dose to CIED ≤2 Gy	Other than low and high risk PM • Electrons or Photons ≤6 MV • PM non-dependent • CIED dose 2–10 Gy • Protons or Photons >6MV • PM non-dependent • CIED ≤10 Gy	• Dose to CIED >10 Gy; • Electrons or photons ≤6 MV, but PM-dependent, and dose to CIED 2–10 Gy • Protons or photons > 6 MV, PM-dependent, and dose to CIED >10 Gy • Electrons or photons ≤6 MV, but PM-dependent, and dose to CIED >2 Gy • Protons or photons >6 MV and PM-dependent or frequent ICD interventions
	DEGRO/DGK[20]	• Non-pacemaker-dependent • ICD without VT/VFib • CIED dose <2 Gy • Pacemaker-dependent • ICD with VT/VFib before/after implantation	•CIED dose 2–10 Gy •CIED dose < 2 Gy	• CIED dose >10 Gy • CIED dose >2 Gy
	AAPM[11]	CIED dose <2 Gy	CIED dose 2 – 5 Gy	CIED dose >5Gy or Neutrons Photon >10 MV
	HRS (NO RISK CLASSIFICATION)[2]	Production of secondary neutrons is the strongest predictor of CIED malfunction in contemporary devices. Non–neutron-producing treatment is preferred over neutron-producing treatment in patients with a CIED to minimise the risk of device reset. Evidence is lacking to define an appropriate frequency of CIED evaluation for a case with a CIED dose <5 Gy.		
	ESC[24]	Non-pacemaker-dependent No frequent ICD interventions Dose to CIED ≤5 Gy		Pacing dependant or frequent ICD therapies Dose to CIED >5Gy

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<table>
<tr><th></th><th></th><th>Low Risk</th><th>Medium Risk</th><th>High Risk</th></tr>
<tr><td rowspan="3">Comparison of preparation steps for radiotherapy by risk classification</td><td>JASTRO/JCS[1]</td><td>• Obtain informed consent
• Consult with cardiologists
• Check CIED identification book
• Classify the risk
• Discuss with a cardiologist regarding response in a case of abnormal operation during radiotherapy
• Radiotherapy staff should fully understand abnormalities of the operation
• Simulation CT performed with the same procedure as diagnostic CT
○ No direct beam to CIED
○ Recommend < 10 MV photon beam and < 20 MeV electron beams.
○ Evaluate total dose to CIED
○ Discuss with a cardiologist whether asynchronous pacing should be used if pacing suppression occurs during irradiation.</td><td>In addition to low-risk actions:
• If there is an ICD function, discuss with a cardiologist whether to stop ICD function during irradiation
• Discuss with a cardiologist whether to perform function checks every week.</td><td>In addition to medium-risk actions:
• Consider relocating CIED for appropriate cancer treatment. Be aware that there is a guideline that suggests CIED relocation is not recommended for a CIED dose <5Gy.
• Discuss with a cardiologist whether to check function after every radiotherapy session.
• For a PM-dependent patient, discuss with a cardiologist whether to prepare temporary out-of-body pacing during irradiation.</td></tr>
<tr><td>AIAC/AIRO/AIFM[19]</td><td colspan="3">• Consider situation
• Use of magnet
• Device reprogramming
• Device relocation
• Presence of electrophysiologist/nurse/technician
• Presence of anaesthetist</td></tr>
<tr><td>DEGRO/DGK[20]</td><td colspan="3">1. Identification of CIED-bearing patient, labelling in patient’s chart, specification of CIED (manufacturer, model).
2. The patient should be made aware of the signs of syncope or dizziness as potential signs of latent CIED defects. In this case, patients should seek immediate advice from their treating cardiologist.
3. Documentation of RT-associated risks in consent form, including risk of radiation-induced CIED failure and potential device replacement surgery.
4. If CIED is located in beam: consult with treating cardiologist; discussion of relocation is advised.
5. Presentation to cardiologist: indication for CIED, examination and documentation of all programmed parameters, pacemaker-dependency (VVI, 30/min), documented episodes of VT/VFib in RAM, percentage of mandatory cardiac stimulation, battery capacity.
6. RT planning: acquisition of CIED in planning CT if feasible, limitation of energy to 6 MV (10 MV) when photons are used, computation/recording of cumulative radiation dose to CIED, no direct placement of CIED in beam.
7. Classification into risk category (low, intermediate, high).</td></tr>
<tr><td></td><td colspan="3"><table>
<tr><th>Low Risk</th><th>Medium Risk</th><th>High Risk</th></tr>
<tr><td>Emergency protocol
• Cooperation between radiation oncology and cardiology
• Personnel qualified for specific procedures for CIED patient</td><td>Examination of CIED before and after every RT session
PM in asynchronous modes (VOO, AOO, DOO)
• Continuous ECG and SpO2 monitoring
• External defibrillator and external pacemaker available, ECG, NIBP, SpO2, programming device</td><td>Surgical relocation or replanning of RT with the goal of reducing CIED dose
If reduction of CIED dose is impossible then consider RT on individual basis
• Cardiologist or anaesthesiologist present
• CIED examination immediately after RT session</td></tr>
</table></td></tr>
</table>

		• Personnel trained to maximise and treat asystole or ventricular fibrillation according to BLS guidelines.	• Transportation of ICD patient with deactivated ATA therapy under surveillance to the cardiology outpatient clinic should remain an exception
AAPM[11]	1. Determine if the patient had prior irradiation proximal to the device area. 2. Nominal x-ray energies lower than (or equal to) 10 MV should be used to avoid neutron production. If high photon energies (>10 MV) cannot be avoided, then the patient should be managed within the High-Risk category. 3. Irradiation with proton or neutron beams should be avoided to prevent neutron production. If used, the patient should be managed within the High-Risk category. 4. Lower dose-rates are preferred. 5. Cumulative dose should be kept at <5 Gy level for CIEDs (ie. Low- to Medium-Risk categories), when possible. 6. Treatment planning should include selection of the appropriate beam angles to increase the distance and shielding of the CIED. 7. Whenever feasible, the generator for the device should be kept at least 5cm from the collimated field edge (including imaging fields) to limit the dose to the device. 8. The use of external lead shielding is not recommended for treatment. 9. If the CIED is more than 10cm from the edge of the radiation treatment area, in vivo dosimetry is not necessary to estimate the cumulative dose to the device (which will be less than 2 Gy) unless non coplanar beams are used or there is some other condition that could unexpectedly elevate the dose to the CIED. 10. If the CIED generator is between 3 and 10cm from edge of radiation treatment area, an in vivo dosimeter should be placed over the device and covered with bolus (typically ≥0.5 cm) to measure dose from the first treatment fraction. 11. If the nearest edge of the CIED generator is closer than 3cm from edge of radiation treatment area (or within the 5% isodose line), the treatment planning system should be used to estimate the maximum dose to the CIED. If the cumulative dose exceeds 2 Gy, treatment planning modifications can be considered, or the patient should be managed according to the Medium-Risk category. If the dose is >5 Gy, the patient should be managed under the High-Risk category.		
HRS (NO RISK CLASSIFICATION)[2]	Prior to initiation of radiotherapy, a complete CIED evaluation should be performed and the treatment team should be informed of: (a) whether the device is a PM or ICD, (b) whether the patient is pacing-dependent, (c) the minimum programmed pacing rate and (d) the maximum programmed tracking and sensor rates. • Non–neutron-producing treatment is preferred over neutron-producing treatment in patients with a CIED to minimise the risk of device reset. • CIED relocation is recommended if the current location will interfere with adequate tumour treatment. However, this is not recommended for a case with a CIED dose<5Gy.		
ESC[24]	Multidisciplinary discussion must consider: • whether the CIED is interfering with the RT dose delivered to the tumour • whether the RT is interfering with CIED function (aim to not exceed 2 Gy to permanent pacemaker and 1 Gy to ICD) • risks of moving the CIED: infection (especially in immunocompromised patients), procedural complications (eg. bleeding with thrombocytopaenia) • Last CIED check <3 months earlier.		

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		Low Risk	Medium Risk	High Risk
Comparison of measures before, during and immediately after irradiation by risk classification.	**JASTRO/JCS**[1]	• Establish an emergency support system that can immediately manage events, including unexpected changes in CIED settings. • At the time of using MV X-rays for verification radiographs, be careful not to expose the CIED to the irradiation field. • IGRT by MV X-ray CBCT is not recommended if the CIED body is in the image range. • For IGRT with fluoroscopy or kV X-ray CBCT using kV X-ray, the same management should be used as that for diagnosis of patients with CIEDs in the facility. • When pacing suppression occurs during irradiation, discuss with a cardiologist in advance whether to use asynchronous pacing. • Observe the patient's condition with an in-room video camera and microphone during each entire radiotherapy session. • Examine subjective abnormalities and pulse after each session. • When CIED settings are changed before irradiation, return to the required settings immediately after irradiation.	In addition to low-risk actions: • Monitor the circulation by an electrocardiogram or pulse oximeter for pulse abnormalities during the first radiotherapy session and, if necessary, continue monitoring for subsequent sessions. • When a CIED has a function as a cardioverter-defibrillator, discuss with a cardiologist in advance whether to terminate this function during irradiation. (Then prepare for an external cardioverter-defibrillator including an AED).	in addition to Medium-risk actions: • In high-risk patients, monitor the circulation by an electrocardiogram or pulse oximeter for pulse abnormalities during each session. • For a PM-dependent patient, discuss with a cardiologist in advance whether to prepare for temporary external pacing during irradiation.
	AIAC/AIRO/AIFM[19]	Audiovisual monitoring • Audiovisual monitoring of patient • For an ICD: suspend tachycardia therapy or use a magnet	ECG/pulse oximeter + audiovisual monitoring. In addition to low risk actions: • Crashcart present during RT • Possibility of external pacing • Trained staff with cardiology expertise can be present within 10 min (if not, patients should be referred to another institute).	ECG/pulse oximeter + audiovisual monitoring. In addition to medium-risk actions: • Consider RT or CIED relocation • In an exceptional case a decision based on manufacture recommendations can be made • Safety measures that are at least those used for medium-risk patients ○ ECD-monitoring during every fraction ○ CIED checked within 24 hours by pacemaker technician.
	DEGRO/DGK[20]	1. Evaluation of radiation dose to CIED during first fraction and comparison with calculated CIED dose. 2. Pacemaker-dependent patients: consider asynchronous stimulation (VOO, DOO, AOO); either through reprogramming or magnet placement (only possible with a pacemaker, two adhesive stripes necessary!). 3. ICDs: Deactivation of ATA therapy throughout each RT session; either through reprogramming or magnet placement (pacemaker stimulation is not affected, two adhesive stripes necessary!). 4. Continuous audiovisual contact. Continuous ECG and SpO2 monitoring in patients with suspended ATA therapy and high-risk patients. Personnel should be able to maximise ventricular fibrillation or asystole and to act accordingly (to initiate BLS until arrival of emergency team). 5. Availability of cardiologist and programming device.		

	6. Emergency protocol: immediate notification/activation of a reanimation team, high-risk patients need continuous presence of cardiologist, anesthesiologist, emergency physician. 7. CIED examination after every RT session, including reprogramming and reactivation of initial settings or anti-tachycardia therapy.		
	Low Risk	Medium Risk	High Risk
	• Emergency protocol • Cooperation between radiation oncology and cardiology • Personnel qualified for specific • procedures for CIED patients	• Examination of CIED before and after every RT session. • PM in asynchronous modes (VOO, AOO, DOO) • Continuous ECG and SpO2 monitoring • External defibrillator and external pacemaker available, ECG, NIBP, SpO2, programming device • Personnel trained to maximise and treat asystole or ventricular fibrillation according to BLS guidelines.	• Surgical relocation or replanning of RT with the goal of reducing CIED dose • If reduction of CIED dose is impossible then consider RT on individual basis • Cardiologist or anaesthesiologist present • CIED examination immediately after RT session • Transportation of an ICD patient with deactivated ATA therapy under surveillance to cardiology outpatient clinic should remain an exception
AAPM[11]	• Resuscitation protocol. • Pacemaker magnet, pulse oximetry and AED available at treatment unit. • Close monitoring of the CIED patient with an audio-visual system during treatment. • Communication with cardiology/electrophysiology ICD patients: consult with cardiology/electrophysiology on setting program tachycardia OFF or the use of magnet.	*Low-Risk* requirements *AND* • Formal consultation with cardiology/electrophysiology. • Pacing-dependent: consult with cardiology/electrophysiology on the use of magnet and pulse oximetry. • Appropriate cardiac support available to manage complications from potential CIED malfunctions.	*Medium-Risk* requirements *AND* • ECG weekly monitoring. • Trained staff examines ECG. • Cardiologist/pacemaker technologist should be available, if needed.
HRS (NO RISK CLASSIFICATION)[2]	Continuous visual and voice contact is recommended during each treatment fraction. Cardiac monitoring for pacing dependent devices.		
ESC[24]	CIED Evaluation before RT Audio-visual monitoring during		CIED Evaluation before RT ECG and/or pulse oximetry and external pacing available during RT sessions CIED evaluation weekly during RT.

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		Low risk	Medium Risk	High Risk
Comparison of timing of functional checks	**JASTRO/JCS**[1]	• After the first radiotherapy session. • Discuss with a cardiologist whether to check function after 1–6 months.	In addition to the low-risk actions: • Check function after about half of the planned radiotherapy is complete. In treatment preparation, discuss with a cardiologist whether to check function every week.	• In addition to the medium-risk actions: Check function every week. In treatment preparation, discuss with a cardiologist whether to check function every time radiotherapy is performed.
	AIAC/AIRO/AIFM[19]	• In office/remote evaluation after 1st session • At half course & at the end of RT • After 1 month • After 6 months	• In office/remote evaluation after 1st session • At half course & the end of RT • After 1 month • After 6 months	• In office/remote evaluation after • Weekly • At the end of RT course • After 1 month • After 6 months
	DEGRO/DGK[20]	1. Final examination (threshold levels, sensing and stimulation parameters, lead impedance, battery capacity), reprogramming of CIED. 2. Asynchronous stimulation for no longer than necessary (competitive stimulation against intrinsic heart rhythm may cause malignant ventricular arrhythmias; R-on-T phenomenon). 3. Analysis of CIED irregularities in connection with RT and forwarding of data to manufacturer; note that clinically insignificant changes in parameter settings may precede CIED defects. 4. Exchange of CIEDs with significant defects even if the malfunction is temporary and full device recovery is observed. 5. Repeat examinations 1, 3 and 6 months after RT; telemetric surveillance if available. 6. Education of patient with regard to clinical symptoms of CIED failure (irregular or slow cardiac rhythm, dizziness, syncope), emergency sounds emitted by CIED.		
		Low Risk	Medium Risk	High Risk
			Examination of CIED before and after every RT session.	CIED examination immediately after RT session.
	AAPM[11]	CIED interrogation before 1st fraction and after last fraction.	CIED technologist to interrogate the device at mid- treatment.	ECG weekly monitoring. Trained staff examines ECG. Cardiologist/pacemaker technologist should be available, if needed. CIED technologist to interrogate the device weekly once the device receives > 5 Gy.
	HRS (NO RISK CLASSIFICATION)[2]	• A complete CIED evaluation should be performed at the conclusion of the course of radiotherapy. • Perform weekly complete CIED evaluations for patients undergoing neutron-producing treatment. • It might be reasonable to perform a complete CIED evaluation weekly for patients who are pacing-dependent and are undergoing non-neutron-producing treatment.		
	ESC[24]	• CIED evaluation <3months prior Radiotherapy • Weekly interrogation for high-risk patients • CIED check-up after completing radiotherapy		

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Appendix B: Manufacturer Operating Manuals and Recommendations

Summary of Recommendations from major CIED manufacturers in the UK
(Adapted from ESC, 2021)

Recommendations	Medtronic[12]	St. Jude/Abbott[13]	Boston Scientific[14]	Biotronik[15]
Maximal PPM Dose	5 Gy	No Safe dose	No Safe dose (2Gy used as reference)	2 Gy
Maximal ICD Dose	1-5 Gy depending on model	No Safe dose	No Safe dose (2Gy used as reference)	2 Gy
Maximal beam energy	≤ 10 MV	Not Stated	Not Stated	≤ 10 MV
Lead shielding of the device	No (ineffective against neutrons)	Not Stated (reduction in device dose is recommended)	All available shielding options	Yes
Inactivation of anti-tachycardia therapies	Yes	Yes	Yes	Yes
Heart rhythm monitoring RT	Not Stated	Yes	As determined most appropriate by physician team	Yes
Manuals	Link	Link	Link	Link

Appendix C: Pacing Dependency

Recommendation:

The pacing clinic is responsible for advising the clinical oncologist on patient's dependency and whether a pacing check will need to be performed. The check should happen before commencing radiotherapy to reassess the patient's dependency and whether device reprogramming for ICD pacing-dependent patients is required. For many patients with modern devices the pacing department will be able to interrogate the device remotely.

If this check has not been performed within 6 weeks of the device being implanted, the device must be checked with the pacing clinic prior to the patient's first treatment and preferably prior to their treatment planning.

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.

A full CIED evaluation including assessment for all lead parameters, a determination of battery status and evaluation of pacing dependency of the patient by the local pacing team should be performed.

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 turns symptomatic in case of a (sudden) failure of the CIED's pacing function[11]. A frequently-used definition and the one quoted in the 2018 Italian consensus paper 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). Additionally, spontaneous activity/underlying rhythm is a reliable marker, which pacing clinics use as part of CIED checks and is therefore easily accessible. The majority of patients are not pacing dependent based on this definition and as such, if their device was temporarily turned off or potentially damaged they would not come to serious injury or death from sudden CIED failure[19].

In a single centre Italian observation study, 127 patients with an implanted CIED underwent radiotherapy over a 14-year period, for a total of 150 radiation courses. Pacemaker dependency was reported in 21/127 (16.6%) although the definition of dependency is not provided, a common failing of the literature[16].

PM dependency is considered a risk factor during radiotherapy although malfunctions only weakly correlate with radiation dose. It is the cardiology team's responsibility to state the patient's device dependence to facilitate appropriate management during radiotherapy.

Appendix D: Out-of-Hours and Emergency Recommendation

Clinicians should obtain as much information as possible from the patient in relation to the type of CIED.

IF NO INFORMATION IS AVAILABLE, PROCEED WITH RADIOTHERAPY.

Where possible, use continuous cardiac monitoring.

For ICDs a therapeutic doughnut magnet must be placed over the device during the exposure. The therapeutic magnet must be removed on termination of the treatment by the clinician or appropriately-trained radiographers in charge of on-treatment monitoring.

In order to reduce the risk of malfunctions and keep the dose to the CIED to less than 5Gy, radiotherapy centres must determine distances between field edge and CIED PRV for which the dose will be below the specified limit.

The patient must be referred to their pacing clinic for device check after treatment delivery. The clinician or appropriately-trained staff should seek advice from the pacing clinic prior to the patient's next treatment.

Appendix E: Device Relocation

“Should the device be relocated?” is a question occasionally raised for CIED patients undergoing radiotherapy. Although CIED malfunctions only weakly correlate with radiation dose, avoiding dose to a CIED might compromise dose delivery to the tumour. CIED relocation in this situation is for the purpose of ensuring adequate tumour treatment.

There is no consensus on when a device should be relocated. An informed discussion between the patient, the clinical oncologist and the CIED cardiologist is needed to decide whether CIED relocation should be performed as the procedure is not without risk.

How common is it to relocate in real-world setting?

Thankfully the need to relocate a device is rare. In a large clinical series that assessed the effects of scatter radiotherapy on CIED function, surgical relocation was undertaken if the radiation beam was <2.5cm from the implant site (unless clinical factors or comorbidities precluded relocation). All patients with CIEDs undergoing radiotherapy over a 7-year period were observed. Only 5/69 (7%) patients required device relocation because the CIED was directly within a radiation treatment field. Importantly, complications of device relocation were not recorded[29].

In a single centre Italian observation study 127 patients with an implanted CIED underwent radiotherapy over a 14-year period, for a total of 150 radiation courses. Only 2/127 (1.6%) patients underwent planned CIED relocation (in 2013 and 2015). These decisions were made by a multi-disciplinary group comprised of cardiologists and radiation oncologists, because the CIED was deemed too close to the treatment volume and could have potentially interfered with the radiotherapy adequacy. Interestingly, the authors comment that, as a consequence of advances in delivery of radiotherapy and the accumulated experience with CIEDs, these relocations would likely not have been necessary today[16].

In a Danish population-based cohort study utilising The Danish National Patient Registry, 560 CIED recipients undergoing all forms of external beam radiotherapy at four oncology departments in Western Denmark were followed. Precautionary device relocation from the radiotherapy field was performed in 3.5%. At least one new lead was implanted in 20 (83.3%) procedures[17].

Technical aspects

There are various techniques for relocating a CIED generator. In some cases, the generator can be moved away from the field if there is enough redundant lead within the pocket; lead extenders can be used to facilitate device relocation although this is far from ideal. The generator can be removed and a new implant placed on the contralateral side leaving the original leads in situ. In exceedingly rare instances, the leads can be extracted, and the system moved elsewhere if needed. If relocation is deemed necessary, the optimal timing of device relocation in terms of treatment delay due to wound healing has not been addressed in the literature.

When to consider relocation?

The 2018 Italian consensus document recommends that if the CIED is localised within the treatment field, device relocation should be considered (even by just a few centimetres) before radiotherapy, mainly to avoid interference with adequate tumour treatment rather than CIED damage[19]. The HRS 2017 expert consensus report also recommends CIED relocation if its current location will interfere with adequate tumour treatment[2]. It also specifically advises that CIED relocation is not recommended for devices receiving a maximum cumulative dose of <5 Gy.

Risks of relocation

CIED generator replacements are associated with notable complication risks, particularly those with lead additions. The greatest clinical concern is risk of CIED infection, which has a 30-day mortality of 5–8%[21].

The data support careful shared decision-making before device re-intervention. Specific data on complications of device relocation are limited, although the procedure is comparable to a generator replacement with modification of the device pocket +/- new lead insertion.

A meta-analysis of pooled data, including over 200,000 patients in 60 studies presented in the international consensus document on how to prevent CIED infections, classifies risk based on patient- and procedure-specific factors[25]. Patient-specific factors include malignancy, renal insufficiency, diabetes mellitus, chronic obstructive pulmonary disease, corticosteroid use and history of previous infections[21].

A small prospective randomised single blind control study evaluated the effect of pocket capsule removal (decortication) in 258 patients undergoing generator replacement procedures. A significant increase in acute haematoma formation was observed in the cohort undergoing capsule removal, a procedure that has many parallels to device relocation[22].

The REPLACE registry prospectively assessed predefined procedure-related complication rates associated with elective CIED replacements over 6 months of follow-up in 72 US centres. Two groups were studied: those without (cohort 1) and those with (cohort 2) a planned lead addition. Major complications occurred in 4.0% (95%CI, 2.9-5.4) of 1031 cohort 1 patients and 15.3% (95%CI, 12.7-18.1) of 713 cohort 2 patients. In both cohorts, major complications were higher with ICD compared with pacemaker generator replacements. Complications were highest in patients who had an upgrade to, or a revised, CRT device (18.7%; 95%CI, 15.-22.6). No peri-procedural deaths occurred in either cohort. The 6-month infection rates were 1.4% (95%CI, 0.7-2.3) and 1.1% (95%CI, 0.5-2.2) for cohorts 1 and 2 respectively[23].

The data support careful shared decision-making before device relocation is undertaken.

Device extraction

It is rare to contemplate full device extraction to facilitate delivery of radiotherapy and such a procedure is outside the scope of this document.

Appendix F: Magnet Response

Pacemakers: Placing a magnet over a pacemaker will cause the device to pace at an asynchronous (fixed) rate. This means during application of the magnet the pacemaker will not sense the patient's heart rate or any other external signals. The specific rate depends on the manufacturer, the model and the battery status of the device. Removal of the magnet will restore programmed device function. Typical magnet rates vary between 85-100bpm, depending on current battery status.

In pacing-dependant patients, it is advisable to use a magnet to provide stable pacing (or reprogramme the pacemaker before and after radiotherapy). Other patients are not dependent on their pacemaker - their underlying rhythm is stable and fast enough for it to be safe to leave the pacemaker's settings untouched. Magnet application in this group of patients could do more harm than good as the fixed pacing rate could compete with the patient's own heart rate and could cause symptoms or arrhythmias.

Implantable Cardioverter Defibrillators (ICDs): A magnet will not have any effect on the pacing function of an ICD. A magnet will disable the shock therapies of an ICD. Normal programming will be restored once the magnet is removed and the shock therapy will be re-activated automatically. Some ICDs will emit an audible tone upon placement of a magnet.

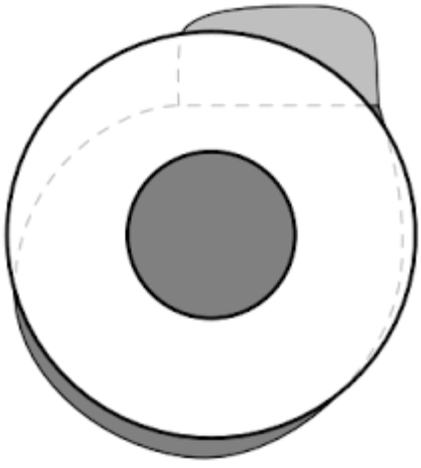
It is important that the shock function of the ICD is deactivated during any procedure that could introduce an external source of noise. A magnet is an acceptable way of doing this given that the patient is monitored during the treatment.

It is important to monitor closely for tachyarrhythmias (fast heart rhythms) while the ICD is disabled as the ICD will not treat these. A defibrillator should *always* be available on stand-by whenever an ICD is deactivated.

In the situation that a patient with an ICD is also dependent on their device for pacing, reprogramming *will* be required, as the magnet does not influence pacing parameters in ICDs. Because of the aforementioned need for monitoring, this is most efficiently done by a cardiac physiologist within the radiotherapy department, to avoid the need for monitored patient transport.

Magnet placement: a medical-grade (typically 90 Gauss or above at 40mm from the surface) doughnut-shaped magnet should be securely taped directly over the device for the duration of the radiotherapy session.

NB: In some models of device, the response to a magnet is programmable. This means the above information may not hold true. It is very rare that a device would ever be programmed to deliver anything other than its standard response to a magnet, but it is possible. The magnet response of the device will be checked by the device clinic prior to the start of radiotherapy sessions.



Placement of magnet over CIED (Boston scientific, 2021)

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