Management of RT patients with implanted cardiac devices: From recommendation to implementation

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Outline

- CIED relocation. An option?
- CIED malfunction and clinical significance
- Pacing dependency
- ICD therapy. On or off?
- Patient management
  - The patients perspective
  - Prior to treatment
  - During/after treatment

CIED relocation. An option?

CIED implantation risks:

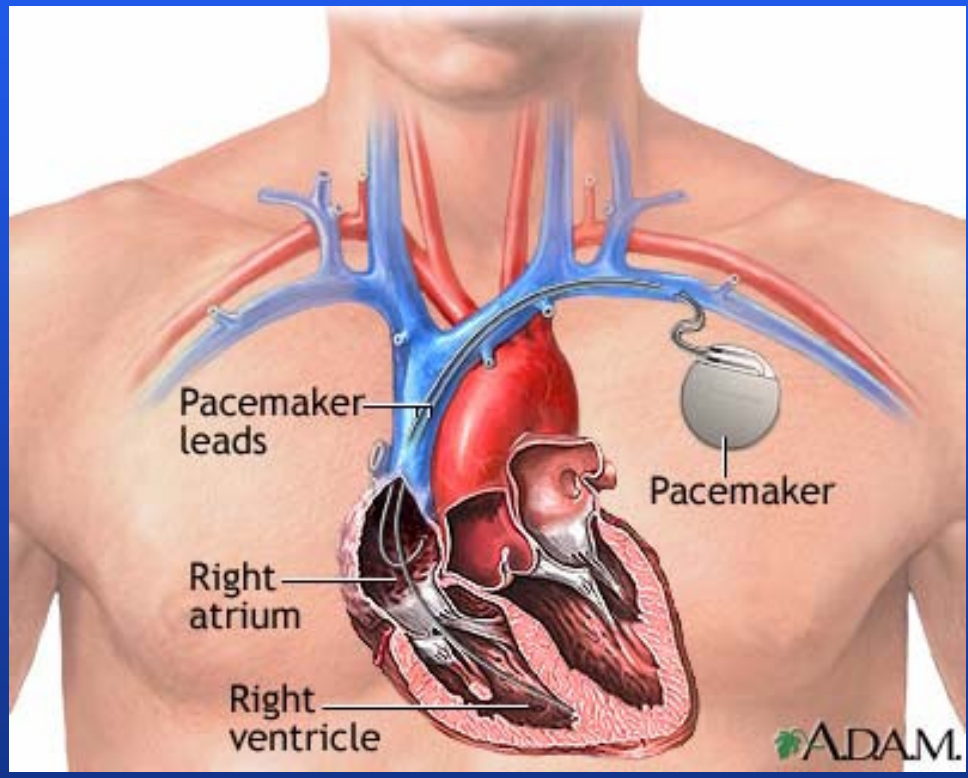
- 1-2% of patients serious complications (0.3% mortality) requiring acute thoracic surgery (Wilkoff et al., Heart Rhythm 2009;6:1085-1104).

CIED re-implantation on other side risks:

- infection (0.4% – 4.0%) which necessitates removal of the device
- pneumothorax (0.8%-1.7%) (de Bie et al., Heart Rhythm 2012;9:494-498).

Elective replacement of a CIED:

- 5.8% serious complications (Gould et al. JAMA 2006;295:1907-1911)
- Chance of infection increases with subsequent CIED replacement (Borleffs et al., Pacing Clin Electrophysiol 2010;33:1013-1019).



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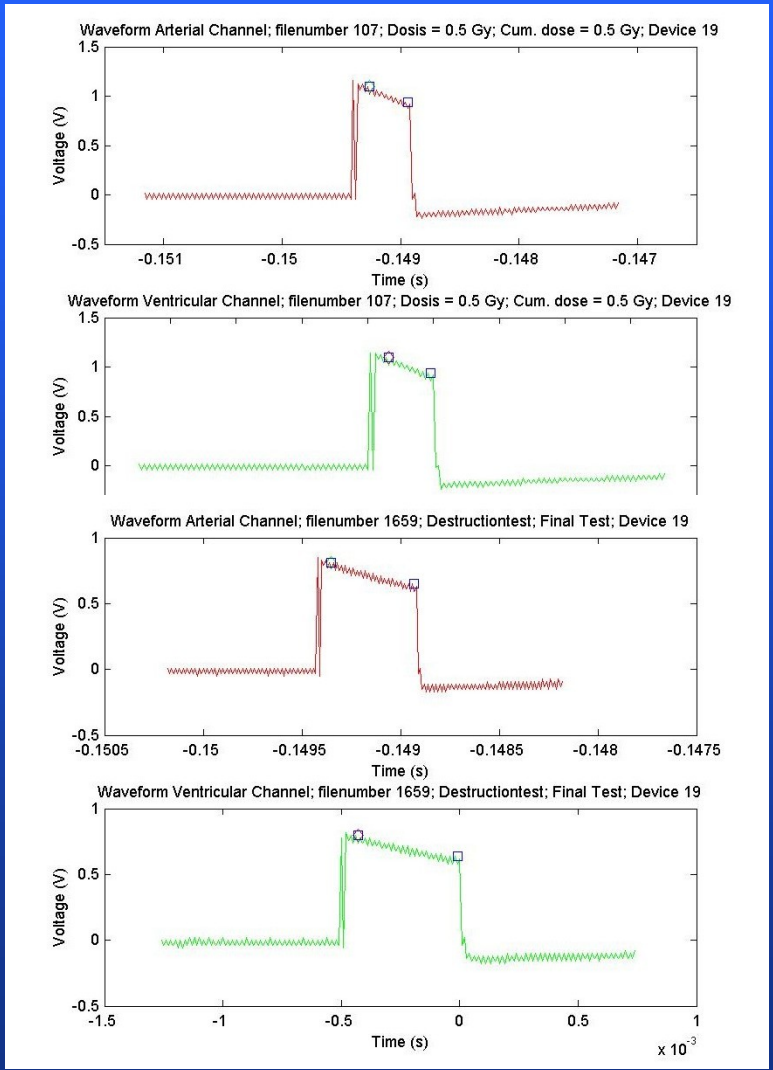
Types of failure in relation to clinical significance

Pacing pulse

- All amplitude deviations of more than 25%.
- Complete loss of signal (POF).
- All pulse duration changes of more than 25%.

The pulse energy has to be sufficiently high to stimulate the heart. Usually, the pulse energy (pulse amplitude times pulse duration) is programmed at an approximately 50% higher value than the lower threshold value to stimulate the heart of an individual patient. An energy drop of 25% will therefore probably not be noticed by the patient. However, it might indicate that the pacemaker has been damaged.



Hurkmans et al., Radiother Oncol 2005;76:93-98

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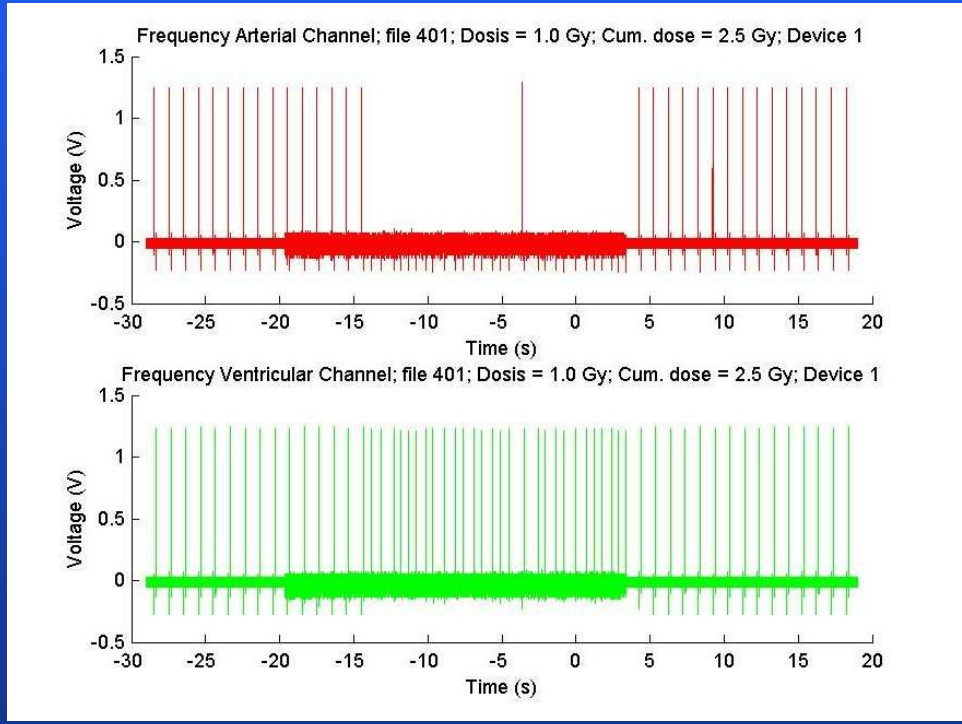
Types of failure in relation to clinical significance

Pacing frequency

- All frequency changes of more than 10% before or after irradiation (POF).
- Inhibition during irradiation only shorter than 5 s.
- Inhibition during irradiation only longer than 5 s.
- More than a single inhibition before or after irradiation (POF).

If the pacing frequency becomes too high, ventricular tachycardia may occur which can lead to a life threatening decrease of blood pressure (Zweng et al., Angiology 2009;60:509-512.).

Inhibitions during irradiation might be due to the direct irradiation of the pacemaker and might not be seen if the pacemaker is placed outside the field. Frequency changes or inhibitions before or after irradiation indicate that the pacemaker is damaged. A pacemaker technician should inspect the pacemaker.



Hurkmans et al., Radiother Oncol 2005;76:93-98

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Types of failure in relation to clinical significance

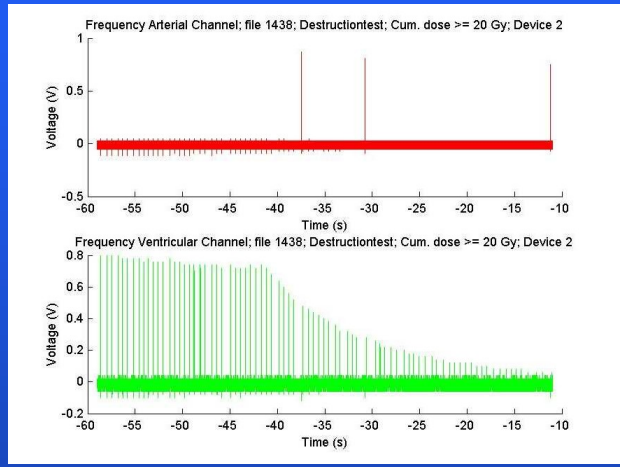
Sensing threshold changes larger than 25%.

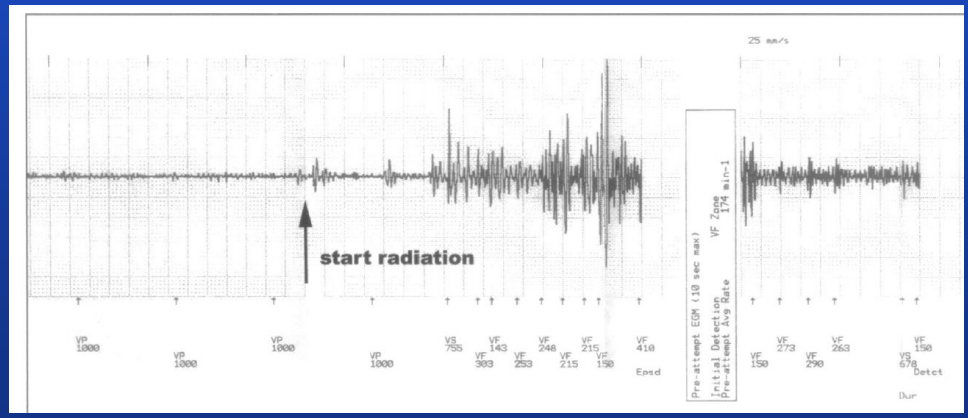
Telemetry

- Temporary loss of telemetry.
- Permanent loss of telemetry (POF).

Miscellaneous

- Battery problems
- Lead impedance changes
- Soft errors / Reset to factory settings
- Erroneous VT/VF detection





Hurkmans et al., Radiother Oncol 2005;76:93-98

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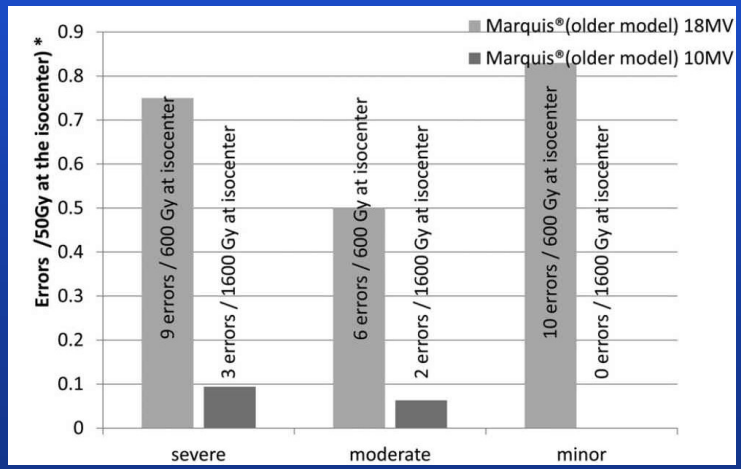
Types of failure in relation to clinical significance

Soft errors - Single event upsets caused by neutrons

Table 1 Classification of device errors

Error type		Feature	Outcome
Hard error		Damage to hardware of device	Permanent stopping in generating pulses or loss of control with computer
Soft error	Severe reset (back-up mode)	Accidental overwriting of protected memories in RAM (essential for setup)	Beep: on Mode: changes to safety back-up (eg, VVI 65 bpm) Correction by computer: needed
	Moderate reset	Interference with protected memories in RAM	Beep: on Mode: no change Correction by computer: unnecessary
	Minor error	Slight memory change cannot be detected by the computer directly	No change in parameters of the device



18 MV neutron dose 14-20 times higher than for 10 MV beam!

Hashii et al., IJROBP 2012 in press

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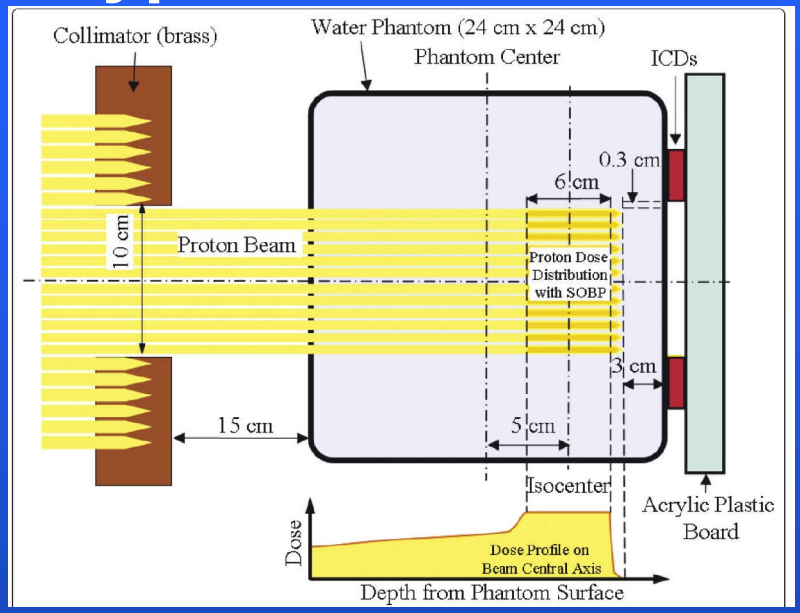
Types of failure in relation to clinical significance



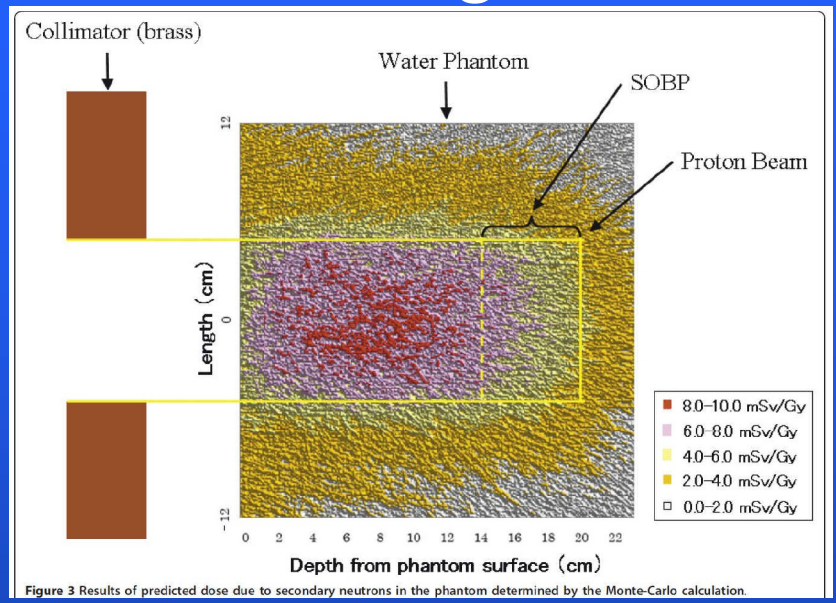


Figure 3 Results of predicted dose due to secondary neutrons in the phantom determined by the Monte-Carlo calculation.

Table 1 Type, description and total number of ICD errors caused by the secondary neutron from 107 Gy proton beam irradiation for each of four ICDs (Marquis DR 7274, Medtronic, Minneapolis, MN)

Type of error	Explanation	Change in frequency and pulse width	Alarm is sounded	ICD reprogramming	Number of sessions detected by the programmer	Number of errors revealed by analysis of the ICD data logs
Hard error	The ICDs stop generating pulses permanently.	Yes	No	Impossible	0	0
Soft error					13	29
Power-on reset	The ICDs present sudden complete failure and switch over to the safety backup mode.	Yes	Yes	Necessary	8	8
Partial electrical reset	The ICDs show no change in mode of pacing.	No	Yes	Unnecessary	5	7
Minor error	The ICDs show no change in mode of pacing.	No	No	Unnecessary	0	14

neutron dose 1-9 mSv/Gy

Hasimoto et al, Radiat Oncol 2012, 7:10

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Pacing dependency

It is obvious that a complete loss of pacing ability will have major implications for pacing dependent patients. If the underlying heart rhythm is not sufficient, the patient will require cardiopulmonary resuscitation. Often, this is followed by external pacing through intravenously placed leads or external electrodes connected to a temporary external pacemaker.

Pacing dependency

A commonly used definition of pacing-dependency is:

Patients who have no intrinsic or escape rhythm and who may become symptomatic (syncope, arrhythmia, serious injury or even sudden death) when the CIED pacing function fails. (Hauser RG, et al. Heart Rhythm 2006;3:640-644., Lelakowski et al. Cardiol J 2007;14:83-86., Korantzopoulos et al. Europace 2009;11:1151-1155.)

The incidence of pacing-dependency in a mixed CIED population is around 10%.

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Tachycardia therapy: ICD therapy off?

In a study of Borleffs et al., approximately 50% of all ICD patients had ICD therapy at least once in a study with 8 years follow-up (Borleffs *Eur Heart J* 2009;30:1621-1626.).

The moment of therapy is unpredictable, however, assuming the chance of this therapy is constant, ICD therapy occurring at least once during a 6 week course of radiation treatment can be calculated at approximately 0.7%.

Deactivation of the ICD shock function **during the entire radiation therapy period** would lead to a similar chance of withholding a potentially lifesaving shock.

Tachycardia therapy: ICD therapy on?

In the ICD population, approximately 10-20% of patients experience an unnecessary shock within a 5 year follow-up period.

It has been reported that these patients have a loss in their quality of life and may develop psychological complaints as a result (Bostwick and Sola., *Heart Fail Clin* 2011;7:101-108)

Delivery of an unnecessary shock during RT is highly undesirable.

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Tachycardia therapy: ICD therapy on or off?

Off: 0.7% chance on withholding lifesaving shock

On: Chance due to RT on unnecessary shock

Dutch guideline: Off during each fraction (0.005% chance on withholding lifesaving shock)

Patient management

Tondato F, Ng DW, Srivathsan K *et al*. Radiotherapy-induced pacemaker and implantable cardioverter defibrillator malfunction. *Expert Rev Med Devices* 2009;6:243-249.

In addition to these recommendations, based on our experience, we suggest the following:

- Be aware of potential sources of device interference in the RT suite, other than ionizing radiation;
- PPMs and ICDs should be interrogated routinely during RT. This is particularly important in pacemaker-dependent patients, when it should be conducted after each session;
- Heart monitoring capabilities should be made available for high-risk patients undergoing RT;
- We reinforce the importance of keeping the implanted devices out of the radiation field, as recommended.

Extra items:

- **pacing dependency**
- **cardiac equipment**

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Patient management

Wadasadawala T, Pandey A, Agarwal JP *et al*. Radiation therapy with implanted cardiac pacemaker devices: a clinical and dosimetric analysis of patients and proposed precautions. *Clin Oncol (R Coll Radiol)* 2011;23:79-85.

Table 4
Precautionary measures for radiation therapy planning and treatment delivery with implanted cardiac pacemakers

Pre-radiotherapy
Take a detailed cardiac history.
Consult a cardiologist for recording baseline cardiac and pacemaker function (full device interrogation and electrocardiography).
Liaise with a cardiologist and a pacemaker centre to know dependency rates, the need to reprogramme pacemakers and threshold doses.
Assess the necessary level of cardiac monitoring for individual patients.
Estimate the absorbed dose to the pacemaker and keep <10 Gy using asymmetric jaws, blocks, multileaf collimators and wedges wherever appropriate.
Reposition the pacemaker if a safe dose cannot be achieved or if pacemaker is located within 3 cm of proposed radiotherapy portal to avoid inaccuracies in dose calculation.
Notify department personnel involved in direct patient care.
Avoid using magnetic resonance imaging or positron emission tomography in radiotherapy planning as these are potential sources of electromagnetic interference .
Always contour the pacemaker body, electrode and lead separately as an organ at risk.
Treatment on a linear accelerator has a higher chance of electromagnetic interference than a cobalt unit, may be considered in select high-risk patients.
Always opt for another non-radiotherapy treatment modality if it will be safer and equally valid.
Consider using brachytherapy in appropriate cases.

During radiotherapy
Continuous electrocardiography monitoring with beam-on on the first day in the presence of the treating physician especially for class I–II patients.
Daily recording of vitals before and after treatment for all patients (by therapist or nurse).
Inform patient and personnel to report any transient and prolonged cardiac symptoms or signs.
Keep a back-up pacemaker system to tackle an emergency on stand by.
Inform the on-call expert cardiac arrest team for class I pacemaker-dependent patients and in cases where the estimated dose to the pacemaker is >10 Gy.
In vivo TLD or diode measurement to record cumulative dose to the pacemaker.
Regular (weekly) device interrogation and electrocardiography as advised by the cardiologist.
Use a lead apron on a pulse generator as per manufacturer guidelines.
Call pacemaker personnel (at least weekly) to review the electrophysical functioning of the pacemaker
Do not put a cardiac monitor within the treatment room, use long leads to place it outside the linear accelerator.
Do not make injudicious use of electronic portal imaging and gating devices.

Post-radiotherapy
Consult a cardiologist to recording any cardiac and pacemaker malfunctions at the conclusion of radiotherapy.
Assess the need to reprogramme or replace the pacemaker.
Ensure appropriate follow-up checks with the cardiologist for several weeks to detect late failure.

Table 3
Classes of Pacemaker dependency

Pacing independent

	Class I	Class II	Class III
Symptoms	Bradycardia	Asymptomatic	Asymptomatic
Ventricular rate	No intrinsic activity	Ventricular rate <30 beats per minute	Ventricular rate > 30 beats per minute
Abrupt cessation of pacing	Fatal	Not fatal	Not fatal
Emergent/urgent situation	Expected	Not expected	Not expected
Level of cardiac monitoring	Intense and active, before, during and after radiotherapy: cardiac arrest team on call	Routine	Routine
Previous untoward cardiac history	Usually present	Not present	Not present
Pacemaker dependency	Highly dependent	Intermediately dependent	Non dependent

Extra items:

- **pacing dependency definition**

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Patient management

Hudson F, Coulshed D, D'Souza E *et al*. Effect of radiation therapy on the latest generation of pacemakers and implantable cardioverter defibrillators: A systematic review. *J Med Imaging Radiat Oncol* 2010;54:53-61.

- **Treatment**
- ***Equipment to be maintained by the department***
- **1** Cardiac monitoring device (ECG);
- **2** 'crash cart' – including CPR devices; and
- **3** hospital defibrillator with external pacemaker capacity.
- ***Pacemaker and defibrillator patients***
- *Non-pacemaker dependant patients*
- **1** Treatment may be undertaken as per dept protocol.
- **2** Regular device checks are advised after every session
- ideally, at least weekly.
- **3** TLDs performed day 1 to check dose received by the
- pacemaker.

Extra items:

- **pacemaker vs ICD**

Pacemaker dependant patients
1 Cardiac monitoring (ECG) is essential during every treatment session by appropriately trained personnel (with ability to respond to any arrhythmic event).
2 Device checks are advised after every session.
3 If an extreme bradycardia occurs, staff should be prepared to resuscitate the patient using external pacing as required (as a bridge to transvenous pacing and device replacement).
4 TLDs performed day 1 to check dose received by the pacemaker.
ICD patients
1 Use the defibrillator programmer to disable antitachycardia therapy during treatment.
2 Cardiac monitoring (ECG) is essential during every treatment session by appropriately trained personnel (with ability to respond to any arrhythmic event). Monitoring must start as soon as the anti-tachycardia therapy is switched off and continue until the antitachycardia therapy is switched back on after the treatment session.
3 Device checks are advised after every session.
4 If an extreme bradycardia occurs, staff should be prepared to resuscitate the patient using external pacing as required.
5 TLDs performed day 1 to check dose received by the ICD.

Extra “item”: the patients’ perspective

Dutch patient focus group:

• CIED management problems related to radiation therapy of low interest. They are dealing with much more serious health care related problems.

• Some appreciated receiving detailed information while others did not wish to be informed.

• The treating radiation oncologist and cardiologist should together decide and present the best course of individualised treatment to them.

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patient management: patient oriented risk categories

- The patient's risk is not equal to the risk of a CIED defect
- The chance on CIED malfunction mainly increase with dose and are **not** accurately known
- A practical guideline will be easier to implement

	< 2 Gy	2-10 Gy	> 10 Gy
pacing-independent	Low risk	Medium risk	High risk
pacing dependent	Medium risk	Medium risk	High risk

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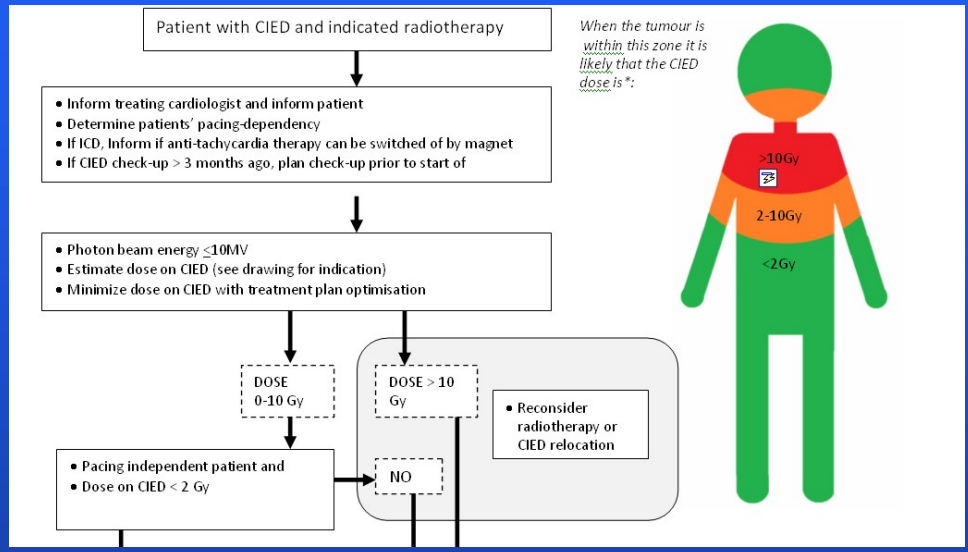
Prior to treatment

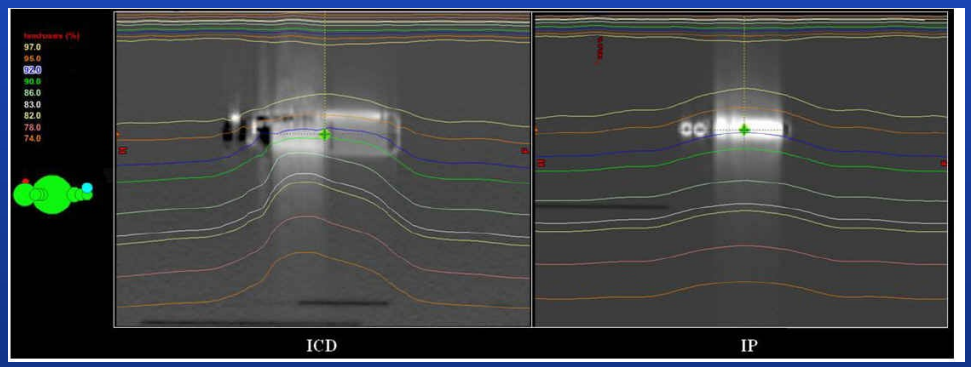
An estimation of the CIED dose should be made by the responsible clinical physicist, which may be supported by a measurement or calculation.

The accuracy needs to be high enough to reliably determine the patient risk category.



Prior to treatment

No heterogeneity correction for the density of the CIED should be made, as this has not been done in the vast majority of articles published about CIED dose in relation to CIED defects.



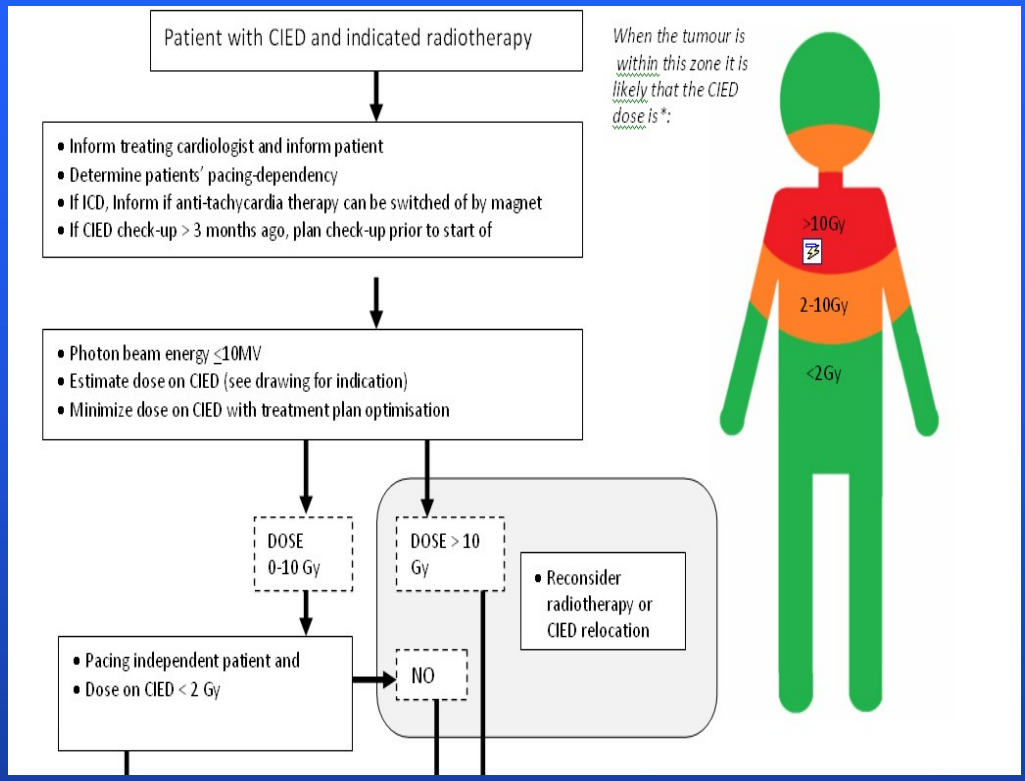


Fig from: Gossman MS et al, **J** OF **APPL.** CLIN. **ME**D. **PHYS.11 (1), 2010**

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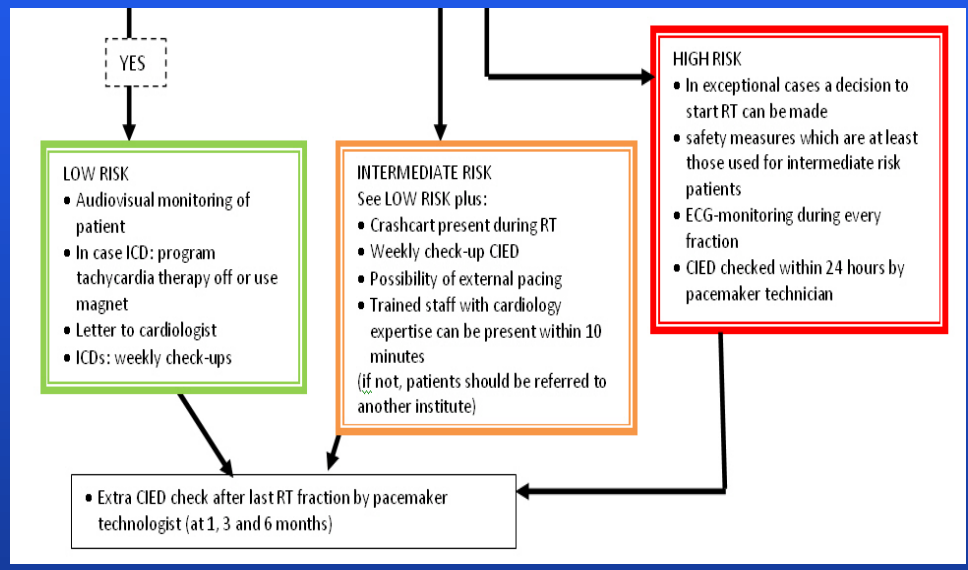
During and after treatment

- ICD might be left on after first fraction if intra-cardiac electrogram during first session is made.
- Medium/high risk: personnel trained in reanimation and a pacemaker technologist and/or cardiologist must be able to reach the patient within 10 minutes of a request in case of an emergency.



Extra item:

- **personnel training**

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acknowlegdements

- AAPM annual meeting scientific committee
- AAPM TG 203 members
- Dutch TG on management of CIED patients
- Academic fund Catharina Hospital RT department

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