

Review of Cardiac Implantable Electronic Devices (CIEDs) and Potential Device Malfunctions due to Radiotherapy

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Learning Objectives

1. Review of Implantable Cardiac Pacemaker (ICP) and Implantable Cardiac Defibrillator (ICD) devices
2. Discuss conditions in clinical use that can induce device malfunctions

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Outline

- Rationale for updating AAPM Report 45 / Task Group 34
- Functionality and components of CIEDs
- Potential effects of ionizing radiation on CIEDs

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Rationale for Updating AAPM Report 45 / Task Group 34

Management of radiation oncology patients with implanted cardiac pacemakers: Report of AAPM Task Group No. 34

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Contemporary cardiac pacemakers can fail from radiation damage at doses as low as 10 gray and can exhibit functional changes at doses as low as 2 gray. A review and discussion of this potential problem is presented and a protocol is offered that suggests that radiation therapy patients with implanted pacemakers be planned so as to limit accumulated dose to the pacemaker to 2 gray. Although certain levels and types of electromagnetic interference can cause pacemaker malfunctions, there is evidence that this is not a serious problem around most contemporary radiation therapy equipment.

Key words: radiation oncology, pacemakers, treatment protocol, complications

Med. Phys. 21 (1), January 1994

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Rationale for Updating AAPM Report 45 / Task Group 34

Published studies show that the radiation sensitivity of contemporary cardiac pacemakers vary, depending on the manufacturer and model.^{6,8,23,34} Since the problem of radiation exposure still affects relatively few (percentage-wise) pacemaker patients, it is unreasonable to propose that all pacemaker manufacturers radiation harden their devices. To do so would incur a significant expense that would eventually have to be passed on to all cardiac pacemaker patients. If necessary, a pacemaker can be moved to an area outside the radiation treatment volume in order to preclude failure from overexposure.

Med. Phys. 21 (1), January 1994

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CIED Vendor Recommendations

| Vendor | Device | Dose Limit (Gy) | |
|-------------------|---------|--|--------------|
| | | 2014 | 2020 |
| Abbott (St. Jude) | ICD | No safe dose (tested to 30 Gy, few errors observed at 20 Gy) | |
| | ICP | | |
| Biotronik, Inc. | ICD | No safe dose | |
| | ICP | 10 Gy | No safe dose |
| Boston Scientific | ICD/ICD | No safe dose | |
| | | | |
| Medtronic | ICD | 1 – 5 Gy (based on model) | 5 Gy |
| | ICP | 5 Gy | 5 Gy |

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Rationale for Updating AAPM Report 45 / Task Group 34

- Average life expectancy of American has increased from 75 (1960 – 65) to 79 years (2015 – 20)
- Between 1993-2009 ICP utilization increased by 55.6%
- In 2014, an estimated 351,000 ICP and 60,000 ICD implant procedures were performed for inpatients in the United States

<http://data.un.org/Data.aspx?q=life+expectancy&d=PopDiv&f=variableID%3a68>

Greenspon *et al.*, Journal of American College of Cardiology, 2012; 60(16): 1540-1545.

<https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2019/02/15/14/39/aha-2019-heart-disease-and-stroke-statistics>

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Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators: A Report of the AAPM TG-203¹

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Role of CIEDs

- Correct for cardiac arrhythmia
 - Bradycardia (heart rate is too slow, < 60 beats per min)
 - Tachycardia (heart rate is too fast, > 100 beats per min)
 - Fibrillation (irregular rhythm)
- If the arrhythmia is serious or of concern, a CIED, such as an ICP or ICD, may be implanted

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Purpose of ICPs

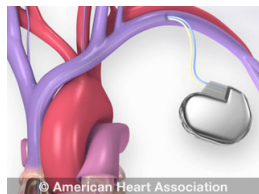
- Sense heart rhythms
- Record
- Therapy
 - Sends an electrical pulses to the heart when arrhythmias are detected to pace the heart → Pacing
 - Some designs – coordinate the chambers of the heart (i.e., ventricles)

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ICP Components

- Leads/electrodes
 - Senses and transmits electrical impulses
- Pulse generator
 - Records heart rhythms
 - Controls therapies
 - Generates pulses to correct for arrhythmia
- Battery
 - Powers the generator



© American Heart Association

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ICP Designs

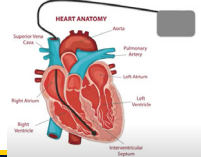
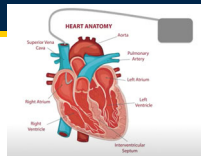
- Single chamber ICPs
- Dual-chamber ICPs
- Biventricular ICPs

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Single Chamber ICP

- Right atrium
 - Sinus node not working adequately, but rest of heart functioning normally
- Right ventricle
 - Normal pulses from the right atrium do not reach the ventricle



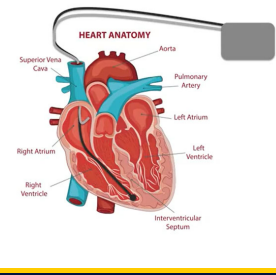
<https://www.youtube.com/watch?v=GfMOa0HvLE0>

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Dual-Chamber ICP

- One lead is placed in the right atrium and a second in the right ventricle
- Coordinates atrial and ventricular contraction, by sequentially pacing atria then ventricle to maximize the heart's pumping ability.



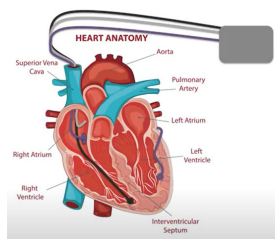
<https://www.youtube.com/watch?v=GfMOa0HvLE0>

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Biventricular ICP

- Leads are placed in the right and left ventricles, and typically a third lead is added to the right atrium.
- The addition of the lead in the left ventricle works to contract the left and right ventricle simultaneously.



<https://www.youtube.com/watch?v=GfMOa0HvLE0>

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Leadless ICPs

- First approved by FDA in 2016
- Advantages of these CIEDs include a reduction in lead and subcutaneous pocket complications, and hospitalization
- Offered by several leading ICP vendors (e.g., Medtronic, Boston Scientific, Abbott [St. Jude])



<http://www.implantable-device.com/2019/05/13/my-take-from-hrs-leadless-pacemakers-are-entering-the-mainstream/>
Bhatia and El-Chami, J Geriatr Cardiol, 2018; 15(4): 249-253.

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Purpose of ICDs

- Sense heart rhythms
- Record
- Therapy
 - Sends an electrical pulses to the heart when arrhythmias are detected to pace the heart → Pacing
 - Some designs – coordinate the chambers of the heart (i.e., ventricles)
 - Delivers high voltage pulse (~800V) to the heart when life-threatening arrhythmias are detected

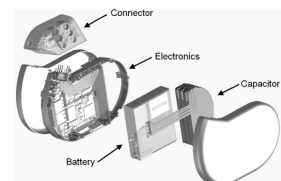
Same functionality as ICPs

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ICD Components

- Leads/electrodes
 - Senses and transmits electrical impulses
 - Provides defibrillation
- Pulse generator
 - Records heart rhythms
 - Controls therapies
 - Generates pulses to correct for arrhythmia
- Capacitor
 - Stores and deliver high-voltage shocks
- Battery
 - Powers the generator



Van Welsenes et al., Neth Heart J, 2011; 19(1): 24-30.

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ICD Designs

- Single chamber ICDs
 - Lead placed in right ventricle
- Dual-chamber ICDs
 - Leads placed in the right atrium and right ventricle
- Biventricular ICDs
 - Leads placed in the right atrium and ventricle, and the coronary sinus which is adjacent to left ventricle

<https://www.webmd.com/heart-disease/atrial-fibrillation/abnormal-rhythms-icd>

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Effects of Ionizing Radiation on CIEDs

- Modern CIED circuits use complementary metal oxide semiconductors (CMOS)
- Pro - CMOS circuits have led to smaller, more energy efficient and reliable CIEDs
- Con - CMOS is known to be susceptible to ionizing and electromagnetic radiation, which may result in transient or permanent device defects

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Effects of Ionizing Radiation on CIEDs

- Ionizing radiation creates excess electron-hole pairs in the SiO₂ layer of the CMOS
- Holes trapped in band gap form aberrant electrical pathways in the insulator
- May result in minor or significant malfunctions

Miften et al., Med Phys, 2019; 46(12): e757-e788.

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Potential Risk Factors

- Clinical conditions
 - Cumulative dose effects
 - Neutron-induced upsets
 - Dose-rate effects
 - Magnetic field effects
 - Electromagnetic interference

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Cumulative dose effects

- Most commonly cited interaction between CIED and radiotherapy

Table III. CIEDs in vivo studies in recent literature.

| Author | Year | Device (ICP or ICD) | Outcome |
|------------------------|------|--|--|
| Sandhu ⁴² | 1994 | 10 ICPs (dual- and single-chamber models, various manufacturers) | 11 ICPs failed with no recovery. First complete failure at accumulated dose of 16.8 Gy |
| Mosier ⁴ | 2002 | 96 ICPs (various manufacturers and models) | 66% amplitude change > 50%, 50% permanent change, 48% showed down rate, 41% silence longer than 10 s, 39% accelerated rate, 27% missing impulses at start of irradiation, 27% signal compatible modification, 17% shape deformation, 5% of all pacemakers were concerned with multiple short circuits, which are considered to be harmful. |
| Harkness ⁴³ | 2005 | 19 ICPs (4 manufacturers) | All ICPs showed a point of failure at or above 90 Gy, except for one at 30 Gy. 5 of 19 ICPs showed a battery replacement warning. Loss of output was the most commonly observed point of failure. ICPs showed a large variation in their sensitivity to radiation. |
| Harkness ⁴ | 2005 | 11 ICDs (4 manufacturers) | First malfunction observed at 0.5 Gy. Sensing threshold changes were often seen as first malfunction, 4 ICDs failed (2.5 Gy, 4 ICDs showed VT or VF, which would have resulted in delivery of a shock. No significant changes in pulse amplitude or pulse frequency were observed. No telemetry problems recorded. |
| Uterwall ⁴⁴ | 2006 | 11 ICDs | Interference detection observed for all ICDs irradiated in the treatment field, noted from the first radiation fraction. 4 ICDs showed VT or VF detection. |
| Koga ⁴⁵ | 2008 | 12 ICDs (3 manufacturers) | No malfunctions observed. |
| Haskins ⁴⁶ | 2002 | 4 ICDs (same manufacturer) | Potential beams with secondary neutrons-20 Soft Error (SEU) were noted. 1 event/15 Gy approx. |
| Haskins ⁴⁶ | 2003 | 8 ICDs (2 models same manufacturer) | 10- and 18-MV photon beams, no hard errors observed, with error more frequently observed at 18 MV. |
| Zorob ⁴⁷ | 2003 | 10 ICPs and 2 ICDs (various manufacturers) | 6 and 18 MV to 150 Gy (2 Gy fraction) dose 6-MV group: One ICP malfunction; 18-MV group: 14 ICP malfunctions at lower dose. 2 ICD malfunctions were noted at low dose level. |

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Miften et al., Med Phys, 2019; 46(12): e757-e788.

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Cumulative Dose Effects

- 18 ICPs from five manufacturers
- Irradiation conditions
 - 8 MV photons
 - 10x10 cm² field
 - 100 cm SSD
 - 2 cm depth
 - 2.8 Gy/fx to 70 Gy or point of failure
- 11 of 18 ICPs experienced permanent failures
- First failure observed at 16.8 Gy

Souliman and Christie, PACE, 1994; 17:270-273

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Cumulative Dose Effects

- 96 explanted ICPs (varying ages)
- Irradiation conditions:
 - 18 MV photons
 - 15x15 cm² field
 - 100 cm SSD
 - 10 cm polystyrene depth (10.2 cm equivalent depth in H₂O)
 - Up to 200 Gy or point of failure
 - Dose rates: 0.05 – 8 Gy/min
- Spread of total dose failures – as low as 0.15 Gy, but 10 ICPs withstood > 140 Gy without failure

Mouton *et al.*, Phys Med Biol, 2002; 47: 2789-2893.

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Cumulative Dose Effects

- 19 new ICPs from four manufacturers
- Irradiation conditions
 - 6 MV photons
 - 10x10 cm² field
 - 100 cm SSD
 - 1.6 cm depth
 - Up to 120 Gy or point of failure
- All devices experienced point of failure at ≥ 90 Gy
 - Complete loss of signal (pacing pulse) - 7 ICPs
 - Lost telemetry capabilities - 3 ICPs

Hurkman *et al.*, Radiother Oncol, 2005; 76(1):93-98.

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Cumulative dose effects

- Potential effects of high cumulative dose
 - Changes in pacing pulse
 - Changes in sensing threshold
 - Temporary or permanent loss of telemetry capabilities
 - Changes in pacing frequency
 - Battery depletion
 - Changes in lead impedance
 - Complete loss of signal

Miften *et al.*, Med Phys, 2019; 46(12): e757-e788.

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Neutron-Induced Upsets

Table III. CIEDs in vivo studies in recent literature.

| Author | Year | Device (ICP or ICD) | Outcome |
|--------------------------|------|--|--|
| Haidichens ²⁸ | 2002 | 4 ICDs (same manufacturer) | Proton beam with secondary neutrons-29 Soft Error (SEU) were noted, 1 event 15 Gy approx. |
| Haidichens ²⁹ | 2003 | 3 ICDs (2 models same manufacturer) | 10- and 18-MV photon beams, no hard errors observed. Soft error most frequently observed at 18 MV. |
| Zaremba ³⁴ | 2003 | 10 ICPs and 2 ICDs (various manufacturers) | 6 and 18 MV to 150 Gy (2 Gy fraction) dose-6-MV group: One ICP malfunction; 18-MV group: 14 ICP malfunctions at lower dose. 2 ICD malfunctions were noted at 150 Gy level. |

Miften *et al.*, Med Phys, 2019; 46(12): e757-e788.

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Neutron-Induced Upsets

Table IV. CIEDs in vivo studies in recent literature.

| Author | Year | Tumor site (Device) | Prescribed dose (Beam Energy) | Dose to device | Outcome |
|-----------------------------|-----------|---|--|---|---|
| Lee ³⁵ | 2008 | Pelvic irradiation (ICD) | 74 Gy (15 MV photons) | <0.1 Gy | Electrical reset potentially by secondary neutrons. |
| Ng ³⁶ | 2008 | Esophagus, Prostate | 45 Gy/2 Gy | Unreported | Power-on reset/pulse width change noted. Reprogramming of device in one case. |
| Gebrian ³⁷ | 2008 | 37 patients treated at various sites including prostate (ICD) | 0.6-31 Gy (9/15 MV photons) | 0.08-2.9 Gy | Patient beams - 10 MV was recommended. |
| Tondan ³² | 2008 | Thyroid, Nose, Lung (ICP) | 26-63 Gy (6-MV photons - possibly) | Unreported | Most cases had minor parameter changes (over/under sensing). Some were more serious than required re-programming. |
| Widradanawati ³⁸ | 2001 | Various sites (ICP) | 45-70 Gy (6-MV photons) | 0.06-40 Gy | No malfunction after 5 months of median follow-up. |
| Ferraz ³⁹ | 2000 | 37 patients with ICPs and 8 with ICDs | 8-78.2 Gy (6- and 18-MV photons, electrons) | 0.3-5.6 Gy | No malfunction reported. |
| Socijsma ⁴⁰ | 2001 | Prospective survey: 60 patients with ICPs and 2 with ICDs | 20-74 Gy (6/15-MV photons, Cyberknife, IMRT) | 0.40-2.1 Gy (8 patients >2 Gy reported) | No malfunction for >2 Gy reported. 1 ICP prostate IMRT 13 MV photon irradiated. |
| Makkar ⁴¹ | 2012/2013 | 69 patients devices placed 4.5-58 cm from treatment field (ICPs and ICDs) | 4-77.7 Gy (electrons, photons, IMRT, SBRT, SHRT) | ICP: 5 Gy (max), ICDs: 1.7 Gy (max)/Mean dose: <2 Gy to all devices | Soft Errors noted in two ICD patients irradiated with 18-MV. |
| Elders ⁴² | 2003 | 15 patient treated in various sites (ICDs) | Doses ranged from 10-70 Gy depending on the site (6/9/18-MV photons) | <1 Gy in most cases. | Soft Errors noted in 29% of treatments with higher energy beams-secondary neutrons suspected in some. |
| Gomez ^{43/44} | 2003 | 42 patients treated in various sites (ICPs and ICDs) | Median prescribed dose 74 Gy (6 photons) | Median estimated: 0.5-5 Gy (mean 146-ade) neutron | 2 ICDs reset, 2 ICPs reset |
| Grant ⁴⁵ | 2005 | 250 patients treated in various sites (ICPs and ICDs) | Dose ranged by site. Primarily 6 and 18-MV | Median 0.50 Gy; range: 0-30.2 Gy | 15 SEU events (attributed to neutrons); 2 unrecoverable; 3 transient noise events. |

Miften *et al.*, I

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Neutron-Induced Upsets

- Prospective survey of 62 patients (60 with ICPs and 2 with ICDs) from 29 institutions
- Device was outside of the txmt field in all patients, but inside of imaging field in 21 patients
- Patients received a total dose of 20 – 74 Gy, median 50 Gy
- Device was evaluated for 52 patients (before, during, or after RT)
- One ICP malfunction was noted – patient treated with 15 MV beam, IMRT to prostate, total dose 74 Gy in 37 fx. Device re-initialized between 46 – 56 Gy.

Soejima *et al.*, J Radiat Res, 2011; 52(4): 516-521.

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Neutron-Induced Upsets

- Retrospective survey of 69 patients (50 with ICPs and 19 with ICDs)
- Device was outside of the txmt field in all patients, 1.5 cm to > 40 cm
- Patients received a total dose of 4 – 77.7 Gy
- Two ICP malfunctions were noted for patients treated with at least one 16 MV photon beam – partial resets of device, one device < 2.5 cm from txmt field

Makkar *et al.*, Heart Rhythm, 2012; 9(12): 1964-1968.
Prisciandaro *et al.*, JACMP, 2015; 16(1): 254-263

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Neutron-Induced Upsets

- Retrospective study of 215 patients (123 with ICPs and 92 with ICDs)
- Patients received a median dose of 33 Gy
- 15 devices (4 ICPs and 11 ICDs) experienced single-event upsets in patients treated with high energy photon beams (15 or 18 MV)

Grant *et al.*, JAMA Oncol, 2015; 1(5): 624-632.

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Neutron-Induced Upsets

Table IV. CED in vivo studies in recent literature

| Author | Year | Tumor site (Device) | Prescribed dose (Beam Energy) | Dose to device | Outcome |
|-----------------------------|-----------|---|---|---|--|
| Law ²⁸ | 2008 | Pelvic irradiation (ICD) | 34 Gy (15 MV photon) | <0.1 Gy | Electrical reset potentially by secondary electrons. |
| Ng ²⁹ | 2008 | Esophagus, Prostate | 45 Gy/72 Gy | Unreported | Power-on resettable with charge reset. |
| Gedham ³⁰ | 2009 | 33 patients treated at various sites including prostate (ICD) | 0.6-41 Gy (16-18 MV photon) | 0.08-2.9 Gy | Reprogramming of device in one case. Proton beams >10 MV was recommended. |
| Tindan ³¹ | 2008 | Thyroid, Nose, Lung (ICP) | 28-63 Gy (6-MV photon — possibly) | Unreported | Most cases had minor parameter changes (over/under setting). Some were more serious than required reprogramming. |
| Walsradzinski ³² | 2011 | Various sites (ICP) | 45-70 Gy (6-MV photon) | 0.08-40 Gy | No malfunction after 5 months of median follow-up. |
| Fernaz ³³ | 2009 | 37 patients with ICPs and 5 with ICDs | 8-79.2 Gy (6 and 18 MV photon, electron) | 0.5-5.6 Gy | No malfunctions reported. |
| Socijans ³⁴ | 2011 | Prospective survey 60 patients with ICPs and 2 with ICDs | 20-24 Gy (6-18 MV photon, Cyberknife, IMRT) | 0.48-2.1 Gy (6 patients >2 Gy reported) | No malfunction for >2 Gy reported. 3 ICDs prostate IMRT 15 MV memory initialized. |
| Makkar ³⁵ | 2012/2015 | 69 patients devices placed 1.5-40 cm from treatment field (ICPs and ICDs) | 4-77.7 Gy (electrons, IMRT, IMRT, SBRT) | ICP: 5 Gy (max); ICD: 1.7 Gy (max); Mean dose: <2 Gy to all devices | Soft Errors in two ICD patients irradiated with 18 MV. |
| Elders ³⁶ | 2013 | 15 patients treated in various sites (ICD) | Doses ranged from 16-70 Gy depending on the site (6-18 MV photon) | <1 Gy in most cases. | Soft Errors noted in 29% of treatments with higher energy beams secondary neurons suspected in most. |
| Gomez ^{37,38} | 2013 | 42 patients treated in various sites (ICPs and ICDs) | Median prescribed dose 34 Gy (6 MV photon) | Median estimated 0.8-Gy (range 0.1-3.0 Gy) | 3 ICDs reset, 2 ICDs reset. |
| Grant ³⁹ | 2015 | 215 patients treated in various sites (ICPs and ICDs) | Dose ranged by site. Primary 6 and 18 MV. | Median 0.50 Gy; range: 0-30.2 Gy | 15 SEU events (attributed to neurons); 2 uncorrectable, 3 transient noise events. |

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Miften *et al.*, Med Phys, 2019; 46(12): e757-e788.



Dose-Rate Effects

- 96 explanted ICPs (varying ages) were studied
- Dose rates: 0.05 – 8 Gy/min
- 70% of ICPs failed at dose rates of 8 Gy/min
- No failures observed at or below 0.2 Gy/min
- Reported failures
 - Amplitude decrease of electrical signal > 10%
 - Silences of electrical signal ≥ 10 s
 - Permanent silence

Mouton *et al.*, Phys Med Biol, 2002; 47: 2789-2893.

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Dose-Rate Effects

- Confounding factors:
 - Cumulative dose: up to a total dose of 200 Gy
 - Devices irradiated in direct beam with 18MV photons

Mouton *et al.*, Phys Med Biol, 2002; 47: 2789-2893.

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Magnetic Field Effects

- Heating at lead tip and tissue interface
- Force and torque on device
- Alteration of device programming
- Inappropriate function and therapies
- Electrical reset
- Component damage
- Death

Santini *et al.*, Pacing Clin Electrophysiol, 2013; 36(3): 270-278.
Indik *et al.*, Heart Rhythm, 2017; 14(7): e97-e153.

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Electromagnetic Interference

- EM noise around modern linacs is minimal
- Potential sources in current practice
 - EMI guidance systems
 - Gating technologies
- Potential effects
 - Inhibit therapies
 - Shut-off of reed switch – result in fixed pacing rate
 - Trigger unnecessary therapy
 - Permanent silence

Mouton *et al.*, Phys Med Biol, 2002; 47: 2789-2893.

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Recommendations

- Cumulative dose < 5 Gy
- Generator should be kept 5 cm from field edge, whenever feasible
- Avoid high energy photons (>10MV) and irradiation with proton or neutron beams
- Maintain low dose-rates to the device (< 0.01 Gy/min)
 - Soft recommendation, there are uncertainties associated with this effect
- Use precautions when MR imaging patients
 - Ensure device is MR conditional and be familiar with conditions in which the device was tested

Miften *et al.*, Med Phys, 2019; 46(12): e757-e788.

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Summary

- As the average lifespan of Americans increase, the number of patients with CIEDs presenting for radiotherapy will continue to increase
- Be familiar with the different types of CIED that are used, and how the device functions
- Understand the potential clinical conditions that can induce CIED malfunctions
- With the proper precautions and patient monitoring, patients may safely receive RT

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