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| Name of Policy: | <u>Patients with implantable devices</u> |  |
| Policy Number: | 3364-134-94 | |
| Department: | Radiation Oncology Chief Executive Officer - UTMC | |
| Approving Officer: | Associate Professor & Chair, Radiation Oncology | |
| Responsible Agent: | Technical Manager, Radiation Oncology | |
| Scope: | Radiation Oncology | |
| | | Effective Date: 4/1/2023 |
| | | Initial Effective Date: 8/18/2003 |
| <input type="checkbox"/> New policy proposal <input checked="" type="checkbox"/> Major revision of existing policy <input type="checkbox"/> Minor/technical revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy | | |

(A) Policy Statement

Special precautions must be followed for all patients undergoing radiation treatments that have surgically implanted (or similar) devices.

(B) Purpose of Policy

To deliver quality and consistent care when delivering radiation therapy to patients with surgically implanted (or similar) devices.

(C) Procedure

1. The nurses shall obtain an accurate patient history regarding surgically implanted (or similar) devices; this will be noted in both the patient intake form in Epic and in the Aria record & verify system by assigning the status icon and creating an alert in the patient’s summary.
2. Determine if the device is electronic or mechanical in nature. For mechanical devices, only dosimetric effects will be evaluated. For electronic devices:
 - a. Make a photocopy of the patient’s identification card that provides the manufacturer’s name and contact information, as well as the device’s serial and model numbers. If the patient does not have this information, contact the responsible physician’s office to obtain this information.
 - b. For cardiologic implanted electronic devices (CIEDs):
 - i. Inform the patient’s cardiologist about the plan of treatment. The nurses must obtain cardiac clearance for CIED patients from the patient’s cardiologist prior to initiating radiation therapy and notate this in the Aria summary alerts.
 - ii. Notify physics and simulation therapist about the presence of a CIED.
 - iii. The patient will be assigned to a risk group based on recommendations from national bodies:

| Patient | Dose region and risk category | | | |
|--------------------|-------------------------------|-------------|-----------|------------------|
| | <2 Gy | 2-5 Gy | >5 Gy | Neutrons present |
| Pacing independent | Low risk | Medium risk | High risk | High risk |
| Pacing dependent | Medium risk | Medium risk | High risk | High risk |

The high risk category as defined by the American Association of Physicists in Medicine (AAPM) and accepted by the American Society for Therapy in Radiation Oncology (ASTRO) is contingent on total accumulated dose and the production of neutrons (only significant for photon energies >10MV).

- iv. Depending on the patient's assigned risk category, appropriate risk mitigation strategies will be employed as spelled out in Appendix A.
 - v. Upon consultation, the frequency for monitoring shall be determined by the cardiologist. Any monitoring needs to be documented in the patient's chart.
 - c. Risk will be assessed for all non-CIED electronic devices, such as insulin pumps, spinal stimulators, *etc.* on a case-by-case basis.
 - d. All electronic devices that fall within 10cm of the treatment field or are expected to receive >5% of the prescription will be measured:
 - i. In-vivo via optically stimulated luminescent dosimeters (OSLDs) or equivalent methods
 - ii. In the treatment planning system (if present on the planning CT)
 - iii. If the device is within 10cm of the treatment field but is not present on the planning CT, special evaluation will be performed.
 - iv. Treatment planning will be performed with the objective of keeping the maximum point dose to less than 5 Gy, preferably less than 2 Gy.
 - v. In-vivo measurements with OSLDs will be performed with 1cm of bolus to simulate implanted depth.
 - vi. If feasible, OSLDs should be placed after pre-treatment imaging; if this is not possible, imaging dose will be corrected for.
 3. For situations when a measurement is necessary, the therapists shall create the measurement documentation at the time of treatment delivery.
 4. Medical physics shall analyze measurements and complete and sign this documentation for physician review.
 5. The physician shall review and approve the documentation and accept the evaluation, order changes based on the evaluation, or order further investigation.

Appendix A

1. Affirmation of risk categories and appropriate actions to be taken:

| <i>Dose to CIED</i> | | |
|--|--|---|
| <2 Gy (Low-Risk) | 2-5 Gy (Medium-Risk) | >5 Gy or neutrons (High-Risk) |
| <ul style="list-style-type: none"> • 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. • CIED interrogation before 1st fraction and after last fraction. | <p><i>Low-Risk requirements</i> <i>AND</i></p> <ul style="list-style-type: none"> • 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. • CIED technologist to interrogate the device at mid-treatment. | <p><i>Medium-Risk requirements</i> <i>AND</i></p> <ul style="list-style-type: none"> • 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. |

[Reproduced from the AAPM’s TG-203 Report “Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators” Med. Phys Volume 46, 2019, e779]

2. In addition, if a patient’s CIED is in the treatment field the Radiation Oncologist will consult with the cardiologist about options, which may include moving the pacemaker out of the field prior to the start of treatment.

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| <p>Approved by:</p> <p><u> /s/ </u> <u>07/14/2023</u> Mersiha Hadziahmetovic, MD Date Associate professor and chair, Radiation Oncology</p> <p><u> /s/ </u> _____ Richard P. Swaine Date Chief Executive Officer - UTM</p> <p><i>Review/Revision Completed By:</i> Michelle Giovanoli</p> | <p>Review/Revision Date:</p> <p>8/2006 5/2008 7/1/2011 7/1/2014 7/1/2017 5/1/2020 4/1/2023</p> <p>Next Review Date: 4/1/2026</p> |
| <p>Policies Superseded by This Policy: 38-94</p> | |