

Radiation therapy and BIOTRONIK CRM devices - pacemakers (IPG), defibrillators (ICD) and CRT-devices

The use of therapeutic radiation on patients with BIOTRONIK CRM-implants is contraindicated due to possible damage and impaired functional safety of the implant resulting thereof. A risk-benefit analysis of the attending physician is mandatory if this treatment should be applied nevertheless.

Background

The number of CRM patients being treated with radiation therapy is rising constantly. Increase in life expectancy, expanded indications and continuously improved technology in Cardiac Rhythm Management, as well as the growing number of people with cancer in the ageing population are leading to an increase in the number of radiation patients with active electrical implants.

The CMOS-technology, which is currently being used for active CRM devices saves space and power and is also more reliable as the previously utilized circuits. This technology, however, is also susceptible to ionizing radiation making transient or permanent damage of CRM devices due to radiation therapy possible.

Influencing Factors

Due to the complexity of factors – e.g. different sources of radiation, device variety, therapy conditions – it is impossible to adopt universally valid guidelines that would allow radiation therapy without effecting CRM devices.

BIOTRONIK has therefore extensively investigated the effects of gamma radiation from a linear accelerator on the newest CRM products Evia and Lumax to support the risk-benefit analysis of the attending physicians.

Effects

The effects of these tests are presented below to illustrate the influencing factors leading to possible damages.

- at radiation energies less than 10 MeV* with a gamma ray dosis of 2 Gy♦ at the implant site, no damages to the device could be determined
- at radiation energies greater than 10 MeV neutrons are generated. Due to scatter radiation these neutrons can occur far outside the radiation beam and lead to device malfunction
- effects on device function at lower radiation energies (less than 10MeV) are dependent only on the total ionizing dose at implant site, and not on the number of treatments
- effects on device function are time-dependent and may occur only at a later time

* MeV – Mega-Electronvolt, unit of gamma ray energy

♦ Gy – Gray, unit of absorbed radiation dose of ionizing radiation [J/kg]

Notes on the performance of radiation therapy for patients with BIOTRONIK CRM devices

Before radiation treatment

- Cooperation between radiologist and cardiologist is recommended
- Gamma rays should be used exclusively
- To avoid the generation of neutrons, gamma rays less than 10 MeV should be used. Note: With higher radiation energies, scatter radiation of neutrons has to be expected despite shielding
- When planning radiation treatment, take into account that the total dose of radiation on the implant site must not exceed 2 Gy
- Avoid direct beam radiation of the device
- Interrogate the device
- Program ICD to 'ICD therapy off'
- Sufficiently shield the device

During radiation treatment

- Monitor the ECG and the blood pressure of the patient or the ECG and the blood oxygen saturation of the patient
- Have an external defibrillator available
- Ideally have a programming device and trained personnel on site

After radiation treatment

- Again interrogate device and reprogram if necessary
- If the activation of the predefined safe program is displayed interference of the device has taken place. The device is basically operational in the safe program, however, ICDs may deliver inadequate shocks
- Device damage may not occur until a later time. Furthermore, the device itself may not be able to identify damage. A follow up shortly after radiation, e.g. on the following day, or device control via Home Monitoring should be considered
- If the device is in the safe program please contact BIOTRONIK in order to reset the device to the program originally installed for the patient