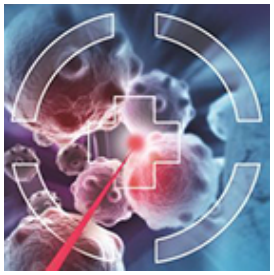

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Challenges in assessing risks for particle accelerators as medical devices

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Particle accelerators used for cancer treatment have made tremendous progress in the recent decades in respect to performance, dose delivery and control techniques as well as their usability within clinical environments. This area is currently experiencing a growing development that promises even bigger achievements in the future regarding treatable indications, cure rates and side effects. More effective medical prescriptions will be technically feasible, with a resulting higher chance of healing and quality of life for the patient. The required higher beam intensities and precision of dose distribution for the treatment of patients increase the consequences and risks for the patients in case of failure of the particle accelerator, caused by either technical faults or human errors. This means that every progress in this field needs to be accompanied by an effective risk management process leading to an acceptable level of residual risk in relation to the expected clinical benefit. The European Medical Device Directive (93/42/EEC) and the European Medical Device Regulation (2017/745/EU) define requirements for dealing with safety and performance for medical devices, including the implementation of risk management processes and application of medical safety standards. Compliance with these requirements turns to be particularly challenging for a particle therapy accelerator. This contribution summarizes the risk management experience gained for the MedAustron Particle Therapy Accelerator with a focus on the results from the risk assessment and a few examples.

Primary authors: FILIPPINI, Roberto (EBG MedAustron GmbH); Dr GRUEBLING, Peter (EBG MedAustron Gmbh); SCHRENK, Mario (EBG MedAustron Gmbh)

Presenter: FILIPPINI, Roberto (EBG MedAustron GmbH)