

High Dose-Rate Remote Afterloader Brachytherapy Devices Approved for Patient Treatment Using Sources Exceeding 10 Curies

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The purpose of this document is to provide a list of high dose-rate (HDR) remote afterloader brachytherapy devices that are approved by the U.S. Food and Drug Administration for patient treatment using sources exceeding 10 Curies (Ci). The NRC will not approve the use of HDR remote afterloaders for patient treatments using sources above 10 Ci if not listed below.

The following HDR remote afterloaders are approved for patient treatment using source activities up to 11 Ci:

- *Mick Radio Nuclear GammaMed (12i, 11i)*
- *Varian VariSource 200 (serial numbers beginning with 200 – 450)*
- *Varian VariSource iX (serial numbers beginning with >500)*

The following HDR remote afterloaders are approved for patient treatment using source activities up to 12 Ci:

- *Eckert & Ziegler BEBIG SagiNova S Version (a.1, a.2, b.1, b.2, c, d)*
- *Mick Radio Nuclear GammaMed (12iT)*
- *Elekta (formerly Nucletron) Flexitron (136149A02)*
- *Elekta (formerly Nucletron) MicroSelectron V2 (105.999)*
- *Elekta (formerly Nucletron) MicroSelectron V3 (106.990)*

The following HDR remote afterloaders are approved for patient treatment using source activities up to 15 Ci:

- *Varian Medical Systems - BRAVOS™*