

decimal eRT Compliance

General

The decimal ElectronRT (decimal eRT) app is developed and maintained following an ISO 13485 Certified Quality Management System. ISO 13485 is a strict standard focusing on patient safety and risk control and it sets requirements for all medical devices, including software, throughout the entire product lifecycle, from design, sales, and maintenance. Adherence to this internationally recognized standard is a large portion of the regulations used by many countries to allow the sale of medical devices in their territories.

Software Development

Adherence to a strong, well-defined Software Development Life Cycle (SDLC) process is a key component to the safe and reliable distribution of medical device software. As such, the development SDLC used for the decimal eRT is compliant with the IEC 62304 standard for Medical device software lifecycle development.

Radiotherapy

In addition to the general purpose medical device and software development standards listed above, decimal eRT is also compliant with the IEC 62083 standard for the safety of radiotherapy treatment planning systems, as well as the IEC 61217 standard for radiotherapy treatment equipment coordinates, movements, and scales. Compliance with these specialized standards help ensure interoperability of the decimal eRT application with other radiotherapy software and equipment and improves software safety by avoidance of common errors, omissions, and inconsistencies through implementation of the controls necessary to meet the requirements of these standards.

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