

decimal Bolus Designer Instructions for Use

Overview and Instructions for Use

The decimal Bolus Designer app is an interactive end user application for designing treatment planning hardware devices for the intended use and primary purpose of enabling radiotherapy professionals to efficiently design patient specific hardware treatment devices for radiotherapy treatment plans. In the most common use case of the software, users will import patient data from existing imaging and contouring software programs, design treatment devices to meet the physician's requirements, and order electron beam shaping devices for fabrication by .decimal.

Furthermore, since the accuracy of information computed and displayed by an application such as this is very important to the proper treatment of patients, it is critical that users have the appropriate educational and clinical experience backgrounds to adequately understand and use the product.

User Responsibilities

It is the user's responsibility to design and test the patient hardware accuracy prior to patient treatment. This general liability on the end users should be understood and communicated to all users and a representative with signatory authority from each facility using the decimal Bolus Designer app must sign a User Agreement stating their understanding and acceptance of this responsibility.

Additionally, a site administrator with signatory authority will be required to sign an End User License Agreement on behalf of the facility indicating understanding of the responsibilities for quality, accuracy, and security described herein.

Clinical Safety

It is the responsibility that the user performs end-to-end testing prior to the clinical implementation of the decimal Bolus Designer app. The user should follow accepted industry guideline for the end-to-end testing. This testing should be performed by qualified personnel.

It is the responsibility of the facility to ensure that all users of the decimal Bolus Designer have had training on the product and possess the appropriate clinical education, experience, and (where applicable) licensure to develop clinical treatment plans and devices. This includes, but is not limited to, the application training provided by .decimal staff.

Warning

It is critical that all users read these Instructions for Use and the User Guide material carefully and

completely and consult the provided User Guides and other training materials to ensure proper use of the application and proper interpretation of results.



Prior to the delivery of any plan on a patient, users are responsible for performing patient specific QA to ensure clinical acceptability of the delivered dose distribution. Since users are responsible for testing the acceptability of the delivered dose before treatment, .decimal, its staff, and representatives shall not be liable for any mis-treatments that may result from use of the system.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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