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.

Intended Use

The decimal Bolus Designer app is an interactive end user application for device creation and ordering for the intended use and primary purpose of enabling radiotherapy professionals to efficiently design patient specific radiotherapy treatment hardware.

User Profile

The decimal Bolus Designer app is a tool to develop radiotherapy treatment plan devices for delivery using an electron linear accelerator. Such plans are generally developed to meet the directives of a physician through a formal documented prescription. As such, the users of this application are expected to be supervised by an attending physician and should themselves be experienced in the physics and dosimetric characteristics of electron radiotherapy. Additionally, users are expected to have formal training in general radiotherapy techniques and best practices, electron therapy specific planning techniques, and general principles of patient safety and care. Most users will have college-level training or degrees, as well as licensure for their particular roles and responsibilities through their state, nation, or professional association. Users should also be well versed in regulations regarding protection of patient health information and have a basic understanding of standard practices regarding computer usage and security.

Users should also be formally trained on the decimal Bolus Designer application, its features, these Instructions for Use, and User Guide prior to performing clinical treatment planning using the application.

Known Limitations

For a list of known system issues and limitations please refer to the following articles for the decimal eRT app. decimal Bolus Designer Known Limitations

decimal Bolus Designer Patient Data Model

The following page describes the hierarchy of data used to manage patient data records within the decimal Bolus Designer application environment.

There are three main levels for how decimal Bolus Designer stores its data:

1. **Patient**
    1. A person receiving medical treatment. A Patient record contains basic personal information and demographics, as well as any number of treatment plans.
    2. This is where the patient name (prefix, given name, middle name, family name, suffix), medical record number (MRN#), sex (male, female, other, any) and date of birth (month, day, year) are stored.
2. **Plan(s)**
    1. A detailed model of an ration therapy treatment. Most aspects of the patient planning information are stored here (e.g. Beams, Devices, etc). A Plan will implement all of the Course prescription and user will lock a Plan to indicate it is ready to proceed to device ordering.
    2. The plan contains a single CT image set and all structure contours (targets and organs at risk) associated with these images.

Hierarchy

A single Patient can have one or multiple [1 - n] number of plans (by importing multiple DICOM data sets for the same patient). This relationship is detailed in the table below:

<table>
<tr><th colspan="3">Patient Data Model</th></tr>
<tr><td rowspan="5">[1]</td><td colspan="2">Patient</td></tr>
<tr><td colspan="2">- Patient metadata information (name, demographics, etc)</td></tr>
<tr><td colspan="2">- Data imported from provided DICOM files</td></tr>
<tr><td rowspan="3">[1 - n]</td><td>Course</td></tr>
<tr><td>- Imported DICOM patient model (CT, Structures)</td></tr>
<tr><td>- Treatment devices</td></tr>
</table>

System Requirements

Details regarding the specific requirements for computers on which the decimal Launcher and decimal Bolus Designer client applications will be installed can be found on the decimal Launcher System Requirements and decimal Bolus Designer System Requirements pages.

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