decimal, LLC i/v decimal ElectronRT User Guide



decimal ElectronRT User Guide

for app version 0.9.0

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decimal ElectronRT Overview



App Version: 0.9.0

Note: This user guide is intended only for the latest version of the decimal ElectronRT app listed above. Please refer to the ElectronRT version history for the complete listing of user guides.





decimal ElectronRT (eRT) is used for treatment planning of electron radiation therapy treatments. The decimal eRT app allows users to specify treatment inputs and display calculation results for the design of electron therapy beams and treatment devices.

Users, access, and permissions for the decimal eRT are managed by the .decimal Direct service.

decimal eRT is not cleared by FDA for Clinical Use



The decimal ElectronRT application has not yet been cleared by the US FDA for clinical use. This guide provides user materials to aid .decimal research and consortium partners in the the performance of their duties regarding product validation and under .decimal's 2019 NIH SBIR Grant.

User Guide

The decimal eRT User Guide provides help material as well as walkthrough guides and a glossary of terms associated with the application.

Getting Started Basic setup and overview of decimal eRT.

Known Limitations Known application limitations, defects, or inconsistencies.

Application Usage Examples and guides for performing common tasks in decimal eRT.

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Instructions For Use

The decimal eRT Instructions For Use outlines the intended use and user requirements of using the decimal eRT app.

Overview Intended use and indications for use of **User Profile** Recommended user education and the application. experience level.

Warning Warning of potential misuse.

Product Features High level features of the decimal eRT app.

Testing Responsibilities Testing responsibilities for ensuring correct setup and configuration of decimal eRT for clinical safety.

System Requirements Local workstation and network system requirements for using decimal ElectronRT.

Commissioning Guide

decimal eRT dose calculations follow the pencil beam redefinition algorithm as described in Pencil-beam redefinition algorithm for electron dose distributions that allows for electron dose calculations using beam limiting devices.

Note: Full commissioning guide coming soon.

Reference Documentation

Dicom Conformance Statement decimal eRT Dicom Conformance Statement. decimal eRT is compliant with the NEMA 2020 DICOM specification. As such, any other systems (e.g.: Record and Verify) that are also compliant with this specification should be able to read the RT Plans generated from decimal eRT.

DICOM-PS3.3 2020b NEMA 2020 DICOM Part 3: Information Object Definitions specification.

About

Acknowledgements Use of third-party

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components in decimal eRT.

Note: This product is not currently cleared by the US FDA for clinical use

Support

For questions, comments, support requests, bug reporting, or to schedule a training session, please contact our customer support team at: appsupport@dotdecimal.com or visit our support portal at dotdecimal.freshdesk.com

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decimal eRT Instructions for Use

Overview and Indications for Use

The decimal ElectronRT (decimal eRT) app is an interactive end user application for electron treatment planning for the intended use and primary purpose of enabling radiotherapy professionals to efficiently design and analyze electron radiotherapy treatment plans. In the most common use case of the software, users will import patient data from existing imaging and contouring software programs, manage physician prescription and intent information, develop an electron treatment plan, analyze the plan to determine how well it meets the physician's goals, 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. Additionally, since each radiotherapy treatment machine produces a unique beam of radiation, there is much responsibility on the end users to adequately commission and test this software over the full range of expected treatment conditions before the system is utilized for patient treatment.

User Responsibilities

It is the user's responsibility to commission and test the dose 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 eRT 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 eRT app. The user should follow accepted industry guideline (such as AAPM TG244) 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 eRT treatment planning system have had training on the product and possess the appropriate clinical education, experience, and (where applicable) licensure to develop clinical treatment plans. This includes, but is not limited to, the application training provided by .decimal staff.

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It is recommended that users follow acceptable global standards during the commissioning of the decimal eRT product. During the clinical set up, the following should be tested to ensure clinical safety prior to treatment:

- 1. Geometric relationships of the hardware machine models
- 2. The dose algorithm
- 3. Data access and storage
- 4. Accuracy of the planning dose systems.

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 eRT app is an interactive end user application for device creation, dose calculation, and many other purposes, for the intended use and primary purpose of enabling radiotherapy professionals to efficiently design and analyze electron radiotherapy treatment plans.

User Profile

The decimal eRT app is a tool to develop radiotherapy treatment plans 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

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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 eRT application, its features, these Instructions for Use, and User Guide prior to performing clinical treatment planning using the application.

Product Features

In the most common use case of the software, users will import patient data from existing imaging and contouring software programs, manage physician prescription information, develop an electron treatment plan, and analyze the plan to determine how well it meets the physician's goals. The primary and most frequently used functions of this software are the data and patient record management (for patient data storage), dose calculation, device design & optimization, user interface controls, and visualization tools.

The decimal ElectronRT software communicates with other radiation oncology software generally by sending & receiving files in various DICOM RT formats. 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. Additionally, since each radiotherapy treatment machine produces a unique beam of radiation, there is much responsibility on the end users to adequately commission and test this software over the full range of expected treatment conditions before the system is utilized for patient treatment. It is this area that provides opportunity for the most likely misuses of the software, which would be incorrect or inadequate commissioning of the application (note many other cases of potential misuse will be designed out of the system by limiting user interactions, providing warnings, and preventing unsafe or incompatible operations). This main misuse is mitigated by requiring that users perform appropriate quality assurance measurements for each patient plan prior to treatment, which should independently confirm that the treatment plan displayed within the decimal eRT app adequately matches the actual to be delivered plan. Please note that such testing is a safety and regulatory requirement in most territories.

decimal eRT User Guide

Overview

The decimal ElectronRT (eRT) application is used for planning of electron radiation therapy treatments. decimal eRT is an interactive end user application that allows users to design treatment plans and electron beam shaping devices (e.g.: bolus, blocks, and intensity modulators) and order those devices for fabrication by .decimal.

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Purpose

The purpose of this document is to provide guidance on the setup, access, and usage of decimal eRT.

Getting Started

Proper use of this software is critical to safe and effective treatment of patients using plans generated by this application. Users are expected to read and understand this complete User Guide including the Instructions for Use, which outlines the general usage principles and limitations of the decimal eRT app. Users must read and understand these instructions before operating the system for clinical use. Refer to each section below for complete details:

Instructions for Use

- Overview and Indications for Use
- User Responsibilities
- Warning
- Intended Use
- User Profile
- Product Features
- Patient Data Model

Precautions

It is the responsibility of those utilizing this application to ensure that all usages of this product relating to patient treatments are performed by trained and qualified personnel only and that such personnel is aware that the quality of any generated treatment plans is highly dependent on the quality and correctness of the input data; therefore if any questions or uncertainties regarding the quality, units, or identification of input data arise, they must be investigated and resolved before the data are used.

Initial Setup

Once decimal eRT has been purchased, .decimal staff will assist with beam model creation, software installation, and user training. Users will generally be trained at two separate levels, system administrators and end users. System administrators will be setup with appropriate access and tools for managing the software, including both the local resources and user accounts. End users will be primarily trained on the details of generating high-quality treatment plans using the local client portion of the application. Additionally, the medical physics team will be trained and assisted in completing the beam modeling and equipment setup processes, which are explained more fully in the Commissioning Guide (this guide is not available at this time).

Installation

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The decimal eRT application is installed via the decimal Launcher client application. Refer to the decimal Launcher user guide for details on using the decimal Launcher.

The main high level requirements for using the decimal Launcher and decimal eRT application are:

- 1. .decimal Direct account credentials
 - 1. This account needs association with a Site ID (.decimal Customer Account number) that has been licensed for use of the decimal eRT application
 - 2. This account needs specific .decimal Permission for accessing the eRT modules
- 2. The decimal Launcher installed

Please refer to the decimal eRT System Requirements page for complete details on hardware and network requirements.

Site Settings and Facility Model

When using the decimal eRT app for the first time users will be required to setup and configure their site facility settings. This includes organization level details (name, report logo, override materials, etc) and specific site details (ordering address, physicians, DICOM export servers, QA options, and machine commissioning).

The Organization Configuration user guide section describes each of the blocks and configuration interfaces.

DICOM Receiver

The decimal ElectronRT application supports importing DICOM patients via a DICOM listener/receiver. Refer to the ElectronRT DICOM Receiver setup guide for instructions for enabling and configuring this method of DICOM patient import into the eRT application.

Keyboard and Mouse Controls

The decimal eRT app utilizes keyboard shortcuts to help streamline many commonly used functions and display controls. A complete listing of these shortcuts along with a full description of the mouse controls is located at the Keyboard and Mouse Controls page.

Application Usage

The following sections are thorough guides providing complete information about each task within the decimal eRT application.

- Launching decimal eRT
- DICOM Patient Import

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- Patient Courses
- Electron Plans
 - Prescription
 - Patient Geometry
 - Points
 - Uniform Thickness Bolus
 - Imaging
 - Density Overrides
 - Electron Beams
 - Electron Block Creation
 - Electron Skin Collimator Creation
 - Electron Bolus Creation
 - Electron Intensity Modulator
 - Electron Beam Normalization
 - Plan Approval
 - Plan Reports
 - Plan QA
 - DICOM Export
- Organization Configuration
- Sandbox Testing
- App Settings

Improper System Usage

When using decimal eRT, as with any complex program, there is the potential for misuse. The decimal eRT app is a radiotherapy treatment planning tool that is intended to be used by experienced and knowledgeable professionals working in the field of radiation therapy.

Known Application Limitations

Below are listed the known application limitations, defects, or inconsistencies.

General

| ID | Affected Version(s) | Description | |
|----|----------------------------------|---|--|
| | 0.0.1 0.0.2 0.0.3 0.0.4 | decimal eRT does not show the MU value for beams and treatment plans. | |

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| ID | Affected Version(s) | Description | |
|----|------------------------|---|--|
| 2 | All | Simultaneous record access: If multiple instances of the application have the same treatment plan record opened, changes will be prevented from being pushed to the patient database if the treatment plan is changed first by another user. This will cause the other simultaneous instances to become outdated. Changes to the local application on outdated instances will be blocked from pushing plan changes to the patient database, but the changes may still appear to have happened in the local application. Users will be warned of their changes being blocked by the error: "Plan revision is outdated. Please close and reopen the treatment plan to continue using this plan." | |
| 3 | All | Random Application Crashes: If the local or network disk cache becomes corrupted the application may crash at seemingly random places while calculations are computing. Clearing the local disk cache within the application settings may help resolve unreproducible application crashes during calculations running. | |

DICOM Import

| ID | Affected Version(s) | Description | |
|----|---------------------|---|--|
| 1 | All | Closing the application immediately after importing a DICOM patient and before the job 'copy_imported_dicom_files_to_course' completes will cause an incomplete CT Image Set when exporting DICOM later in the application. | |
| 2 | 0.9.0+ | Only plan files with a valid bolus in at least one beam will import properly. | |

DICOM Export

| II | Affected Version(s) | Description | |
|----|-------------------------|---|--|
| 1 | 0.0.1 0.0.2 0.0.3 | Exporting local DICOM files and providing no export directory will cause the DICOM files to be exported to the local application installation folder. This will cause the decimal Launcher application to invalidate the local eRT install and require a redownload of the application. | |

Beams

| ID | Affected Version(s) | Description | | |
|----|---------------------|--|--|--|
| 1 | AII | Adding more than one beam with an optimized thickness bolus can sometimes result n the DVH inspection performance being slow. | | |
| 2 | All | Optimized Bolus outside shape is generated to the target size and not the block size. So if manual edits are performed on the block that expand the block shape, the bolus extents may be undersized. This can be remedied by increasing the bolus block outer border. | | |
| | | Skin collimator devices may cause interference with fitting inside of the electron bolus when fitting on the patient surface. This is due to sharp corners that result from a rough patient surface contour. | | |

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Plans

| ID | Affected Version(s) | Description | | |
|----|------------------------|---|--|--|
| 1 | All | (Approved Plans) Users should understand that the eRT application stores only user input information and not computed data. However, since machine models and dose calculation algorithms can change over time, certain calculated data and equipment model data that is considered critical to the patient's treatment record is stored with each plan upon approval. This stored data includes: treatment device shapes (e.g. bolus, collimators, intensity modulators), 3D dose fields per beam, and beam model data. However, it should be noted that data derived from these stored results may be recomputed and is therefore subject to change if Approved Plans are loaded in future eRT versions. One such example would be DVH curves. While the dose is stored and will never change for an Approved Plan, the sampling scheme used in DVH calculations can change over time, therefore DVH curves may change even for Approved Plans if such changes are made in the eRT application. Patient-to-applicator collisions, structure volumes, and QA Dose Calculations are additional examples of information that could change in future application versions as this data remains computed, not stored, even for Approved Plans. | | |
| 2 | 0.0.1 - 0.0.4 | (Unapproved Plans) Unapproved treatment plans created versions earlier than eRT version 0.0.4 will not have the plan prescription filled in (denoted by the error: "Prescription statement not found in plan") resulting in dose not being displayed within the treatment plan displays. Users can resolve this by re-adding the prescription that previously existed in the corresponding Course. | | |
| 3 | 0.0.1 - 0.7.0 | (Approved Plans) Approved treatment plans created versions earlier than eRT version 0.8.0 that contain a skin collimator will no longer be able to load the approved skin collimator when opening the plan. Users will be required to clone the approved plan and re-approve the plan to allow the skin collimator devices to be exported or ordered. | | |

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Data Management (Storage and Caching)

The decimal eRT app has four main components for its data storage that allow secure and efficient data access while sharing patient data and cached calculation results across an organization for multiple users. The four data storage systems are as follows:

| Storage | Description / Purpose | |
|------------------------------|--|--|
| 1. Patient Database | SQLite database for all organization, patients, and treatment records | |
| 2. Patient File Storage | Folder directory that contains all propitiatory data file formats | |
| | Optional folder directory that contains an SQLite database and cached calculation results to share across multiple users | |
| 4. Local (client) Data Cache | Folder directory that contains an SQLite database and cached calculation results | |

At a high level, the decimal eRT application interacts with each data storage element during normal treatment planning as depicted in figure 1.

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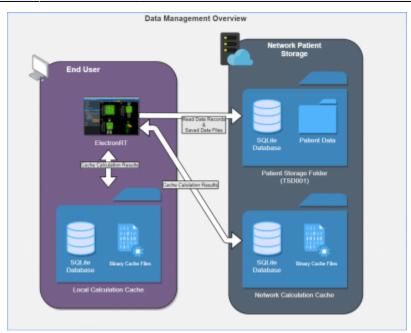


Fig. 1: Data Management Overview

Patient Database & File Storage

The decimal eRT app allows for centralized patient data that is shared between multiple clients (figure 1). The patient storage folder includes an SQLite database for maintaining data records and modification events. By placing this directory on a network location users can share the database across multiple workstations and users.

Patient files are stored in a folder structure that represents the organizational hierarchy of the patient data model. All patient identifying information is encrypted, refer to File Security for more details, in the database and patient data files to prevent unauthorized access to patient data. Files also include 32bit checksums that are linked to encrypted database entries to ensure they are not substituted or modified in an unauthorized manner. Refer to Data Integrity for further details on how data is prevented from modification and changes.

Network & Local Data Cache

The decimal eRT app uses calculation data caching to improve the user experience by loading results from disk rather than recomputing on demand. The calculation disk cache files are comprised of proprietary compressed binary files that represent a completed calculation result. Storing and using the cached calculations results in speedier load times of patient/plan data, beam dose, and hardware devices without having to utilize the processing power of the computer each time a plan is opened. If a calculation result is not found in the calculation cache, the calculation will be performed and the results stored in the cache. The calculation cache is comprised of a local disk cache and an optional network cache (refer to figure 2).

Using the local cache allows for the caching of calculation results to the individual user's workstation and the network cache allows users to share calculation results among all users using the centralized patient database (e.g.: user 1 saves a plan and user 2 opens the plan on a different computer; by saving to the

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network cache, user 2 automatically loads in user 1's results without having to recompute them). Reading data from the local cache allows for the fastest data load time for the end user. Refer to figure 2 for the cache saving mechanics between the local and network caches.

By default when decimal eRT is installed the cache locations are set to the following:

- **Local cache:** C:\ProgramData\decimal ElectronRT\cache
- **Network cache:** None This must be setup in the application settings for each client workstation that is intended to use the network cache

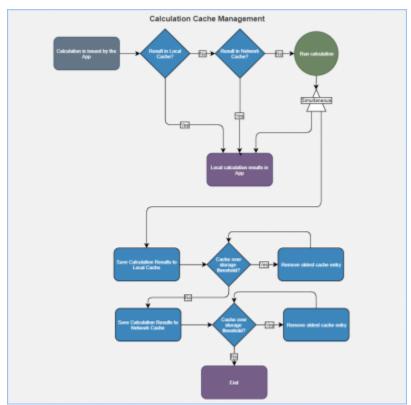


Fig. 2: Data Cache Overview

When the local and/or network cache fills past the set limit within the decimal eRT client, the oldest data will be removed so the cache remains under the limit in the app settings. No plan record data is kept within the local or network cache, so loss of this data only impacts user performance of unapproved plans. On plan approval all critical plan data (devices, dose, etc) is captured in the Patient File Storage.

Clearing the Cache

The local or network cache can be cleared by using the decimal eRT application settings.

In the case of a cache corporation, a manual cache deletion may be required. If the app is unable to open or crashes immediately on open, the local cache should be cleared:

1. Navigate to the cache directory (e.g.: C:\ProgramData\decimal ElectronRT\cache) and manually remove the entire cache folder

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2. Reopen the application and the cache will be rebuilt as the decimal eRT application is used

Data Integrity

Local Data Storage

As with any software application there is always concern with system and data integrity. decimal eRT makes use of caching at various system levels to improve performance and mitigate some of these concerns. Refer to Data Management (Storage and Caching) for details on decimal eRT data caching. While decimal eRT has been designed with security in mind, users should understand that it is still their responsibility to ensure the system is accessed and controlled properly. Following international standards for IT risk management, such as IEC 80001-1, is therefore highly recommended.

Since data integrity is a critical feature for application such as this, the decimal eRT app automatically and continuously saves both the state of the application and the working record data on a timer (triggering every minute or less) as well as on exit of any create or edit event in the application. Additionally, each "save" event creates a new entry in the record's history log in the local database, which provides a log file for editing of all records and ensures that patient records are saved securely. Note it is highly recommended that the application database is hosted on a separate server containing independent, redundant storage drives so that data is not lost in the event of a local system failure or crash.

File Security

The following table describes the file security methods used for decimal eRT data. The subsequent paragraphs provide supplemental details for each item.

| Item | Storage Type | Encryption Type |
|--------------------|---------------------------|------------------------|
| Patient Database | SQLite Database | AES-256 |
| Patient Database | Fields Containing PHI/PII | AES-256 |
| Patient/Data Files | Local/Network File System | AES-256 |

All PHI/PII data (including data files and database fields) is encrypted using AES-256 with an encryption key that is unique for each organization/patient storage location.

- decimal eRT data files: (includes but is not limited to: organization, beam model, patients, course data, plans, etc) Files are encrypted using AES-256 when stored to disk and secured with a checksum stored as an encrypted field in the application database. When files are read from disk, the contents are checked against the corresponding encrypted checksum to ensure the file contents have not been changed, manipulated, or substituted.
- **decimal eRT patient database:** Database is encrypted using AES-256. Additionally, the patient identifying fields within the database are further encrypted using separate AES-256 encryption, adding an additional level of security for patient data within the application database.

Note: The local calculation cache files are a non-human readable, proprietary compressed binary format.

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These files may contain unencrypted patient identifying information. The local cache is purged as the cache fills with data, so exposure to long term data is limited. Workstation level disk encryption (e.g.: bitlocker) is recommended to protect against unauthorized access to calculation caches by providing encryption at rest.

Data Import/Export

Patient data is imported and exported using the DICOM NEMA 2020 standard to ensure the data is transferred error free and securely. Refer to the decimal eRT Dicom Conformance Statement for the supported DICOM tags.

Data Backup Recommendations

Since the decimal eRT app stores data on local file storage on each customer's servers we recommend frequent periodic backups of the file-system in which the patient database and file store are kept.

There are 4 major components for the decimal eRT app that should be considered for data backup using the following Data Duplication or Backup Process. Refer to Data Management (Storage and Caching) for a full detailed explanation of each item.

| Data | Severity of Data Loss | Recommended Frequency |
|------------------------------|-----------------------|-------------------------|
| 1. Patient Database | Critical | As frequent as possible |
| 2. Patient File Storage | Critical | (minimum daily) |
| 3. Network Data Cache | Medium | Daily |
| 4. Local (client) Data Cache | Low | N/A |

.decimal recommends Patient Database [1] and Patient File Storage [2] backups as frequent as possible, at least nightly, to ensure there is no substantial dataloss or interruption of software use. If the [4] Local Data Cache is lost on each workstation the [3] Network Data Cache will be fallen back to by the decimal eRT app. So backup of this data is not necessary. Refer to Network & Local Caching for a overview of the caching mechanic.

It's also recommended that prior to deploying a new release version, a full data backup is performed. While this step should be unnecessary, it's recommended as a precaution in case there are problems with the version upgrade.

Internet Data Transfer

Since electron therapy generally requires frequent use of patient-specific devices that are often not fabricated in-house, there is a necessity to transmit device manufacturing parameters and information to .decimal servers to all for fabrication of the custom devices. In order to protect patient privacy, .decimal's proprietary order file format contains only the minimal data necessary to manufacture each requested device. .decimal values the privacy of patients and security of our customer's sensitive information and

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we believe the best safeguard to protect critical data is to ensure it doesn't leave your facility. As such, no PHI, PII, or any sensitive customer billing/payment information is contained in the order files sent to .decimal.

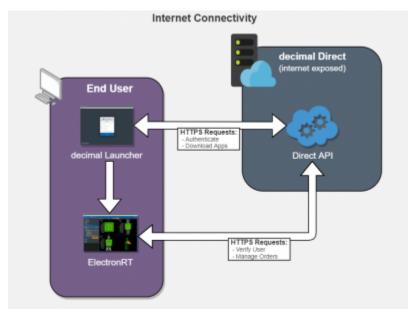


Fig. 3: Internet Data Transfer

Data is transferred to and from the decimal Direct servers using secure HTTPS transfer protocols that guarantee error-free transfer using common industry standard techniques. All data passed to and from .decimal's ordering servers is encrypted during transit and does not contain patient identifying data.

Simultaneous Plan Access

Treatment plans are protected against simultaneous record access and data loss by ensuring an attempted update to plan data is not based on an outdated base file. If the local plan record has been accessed simultaneously by another user and has been modified (committed to the database) by another user, the outdated local plan record will be unable to commit the change until the plan has been updated locally.

Coordinates and Units of Measure

The following is a list of several important items that users should understand in regards to the information displays in the decimal eRT application:

- decimal eRT exclusively uses the DICOM patient coordinate system for position display information (equipment based coordinates are NOT available)
- Local equipment coordinates are available for machine rotational axes (i.e. gantry, couch, and collimator) and users should configure each treatment room to match their actual equipment using decimal eRT site level settings at the time of commissioning
- All linear dimensions are shown in centimeters (cm)

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- All angular dimensions are shown in degrees (deg)
- All radiation dose quantities will be shown with their corresponding units within the application (e.g. Gv or %)
- All date/time values are provided in a yyyy-mm-dd h:m:s format using local time on a 24 hour clock
- All date and time notifications in decimal eRT should match current Windows OS date and time, including proper use of daylight savings time where appropriate (note: decimal eRT will display in 24 hour format, while Windows may display in am/pm depending on local settings)

Data Validation and Limits

Users are responsible for inputting a lot of data into decimal eRT to develop clinical treatment plans. In the course of entering such data, there are opportunities for users to enter incorrect information. Although users are responsible for checking for such errors before clinical treatment, decimal eRT does provide some assistance in ensuring data limitations are met by a plan. Machine energy, beam treatment angle limits, applicator collision detection, SSD limits, as well as electron block sizes and availability are all explicitly limited to user configured ranges within the decimal eRT controls. Additionally, certain incompatible settings, e.g. negative prescription doses, are also explicitly prevented within the decimal eRT user interface.

Despite these many data validation checks, some entries are not able to be validated within the decimal eRT user interface and users should include appropriate checks and warnings in their custom treatment plan reports to ensure such concerns are brought to the attention of all responsible parties before patient treatment begins. Additionally, some checks are implemented as warnings and can be overridden by users. In such cases, treatment plan reports will include a statement such as this (or similar): "CAUTION: SOME DATA ELEMENTS USED WERE OUTSIDE NORMAL RANGE".

Max number of Supported beams

The .decimal ElectronRT App has a limit of 10 treatment beams allowed per plan. Exceeding this amount of beams is considered outside the normal application limits and users will be warned accordingly within the application.

Commissioning Data Field Sizes

The decimal eRT app UI and plan reports will provide a warning to the user if a beam's field size is larger or smaller than the allowable field sizes listed in the commissioning data for the selected beam energy. The warning will appear in the Beams Block next to each beam and as a warning on the Treatment Plan PDF report.

Data Displays and Interpretation

The decimal eRT app is a complex treatment planning system and as such it contains many different displays throughout the plan creation process. The provided User Guide Tutorials provide detailed

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descriptions of each task and display present in the system.

Unauthorized Use

The decimal eRT application will contain sensitive patient information that is protected under various governmental regulations, therefore users must ensure they adequately follow all appropriate and applicable rules regarding how, where, and when their staff may access the application and its data. In order to facilitate proper usage and protections, decimal eRT has a robust user authentication and permissioning system. Since all application and data access requires user login credentials, it is important that a strong password policy is used and that all users understand the importance of maintaining secrecy of their password (i.e. passwords should never be shared among more than one user). It is these user credentials that protect the system and its data from unauthorized access and replication.

Currently the .decimal authentication systems requires passwords to have:

- At least 1 special character (!@#\$%^&*)
- Lower case (a-z), upper case (A-Z) and numbers (0-9)
- Must be at least 10 characters in length

Access Control

decimal eRT uses Auth0 as an Identity-as-a-Service provider for user account management. All user accounts and credentials are managed by the Auth0 service including user creation, password policies, password resets, and secure authentication.

As decimal eRT is deployed on customer workstations the site administrator will be responsible for the installation of the software on the appropriate workstations and the account management of all users at the facility. Each employee should have an individual login and password to access the decimal eRT application that prevents unauthorized access, and account sharing should be strictly prohibited.

User Authentication

Users authenticate and launch the decimal eRT application using the decimal Launcher.

User Sessions

When decimal eRT is launched from the decimal Launcher, decimal eRT is given an JWT authentication token for the logged in user. This token is used to authenticate and perform decimal Direct API requests. This JWT token is issued by decimal Direct and Auth0 and has a built in expiration. When this token expires the user will be logged out of the application and be forced to re-authenticate and relaunch the application using the decimal Launcher. Refer to decimal Launcher's User Guide for details on this authentication token and its expiration.

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Auth0 user credentials are authenticated and validated using the decimal Direct API by decimal eRT each time a user logs in and on recurring timer events. If user credentials are invalid or expired, users will automatically be logged out of the application and prevented from using or accessing any data within the application/system.

Inactivity Timeout

decimal eRT has a built in inactivity timeout that will automatically log the user out if no mouse/keyboard activity has occurred. The timeout setting can be changed in the decimal eRT application settings. Idle workstation locking at the OS level is also recommended for all workstations with access to decimal eRT. While there are inactivity and session timeouts built into the application, workstation idle locking will further protect the system from unauthorized access in-between session timeouts.

Account Management

decimal eRT site managers have the ability to add and remove users to their site. When adding a new user an Auth0 account will be created for the new user and automatically linked to the site. The user will then be notified to set their password following the Auth0 password reset process. Removing a user from a site does not delete the user's Auth0/.decimal account, but removes the account from the site, effectively removing all access to the site's apps, data, and device order history. Refer to the decimal Direct User Guide for more information.

Account Permissions

Account permissions are able to be set by the Site Administrator within decimal Direct. eRT has two levels of account permissions:

- 1. **User Levels**: A high level generic group for the user that provides general access levels
- 2. **Feature Permissions**: A feature by feature granular permission for the user

User Levels

decimal eRT limits the features available to users based on their .decimal account user permission level. The following user permission levels are available:

| Permission Level | Available Permissions |
|-------------------------|--|
| | A default user with normal treatment planning permissions - Recommended permission level for all dosimetry personnel |
| Research | Not applicable for decimal eRT |
| | Elevated user with physics access - Sandbox configuration/user |

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Feature Permissions

In addition, eRT also provides user based permissions for specific features within the application.

| Permission | Description |
|------------------------|--|
| IM Device | Allows the user to use the Electron Intensity Modulator devices when making a beam. |
| | This permission is granted by .decimal staff on the purchase of the Electron Intensity Modulator module |
| Plan Approval | Allows the user to approve and lock treatment plans required to order hardware devices for fabrication |
| Facility Configuration | Allows the user to edit the Organization and Treatment machines, including commissioning data |
| Read Only | Flags the user for read only use of all features in eRT disallowing the editing of the Organization, Course, and Plans |

Known Limitations

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

Release Management (decimal Launcher)

The decimal eRT app is installed and launched from the decimal Launcher. The Launcher program provides the following functionality in regards to decimal eRT:

- 1. Ensures that all users at a site are using the same version of the application
- 2. Ensures that the local app client stays in sync with the latest release version (as set via decimal Direct)
- 3. Provides user authentication and password management
- 4. Provides binary file security to ensure that the application files are not tampered with on .decimal's server or on client workstations (via hashes and checksums). Refer to decimal Launcher's Application Security page for further details.

When an application update is available via the decimal Launcher, the users will be required to install the app in the Launcher. This is accomplished by selecting the *Download* button for the specific app. Within a few minutes, the app should be downloaded and installed locally for the current user account. The user will then be able to launch the released app version from the Launcher.

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

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Releasing a new App Version

When a new application version of decimal eRT is released, users will be notified in the decimal Launcher. This notification serves only to notify users of a newer version of the application and does not result in a newer version being installed for use.

New release versions of the decimal eRT application should be tested prior to clinical deployment following the Testing New Releases guide.

Once an app version has been reviewed and approved for release at a site, the application will be deployed to the decimal Launcher clinical environment following the Updating Applications guide. This will immediately push the app update to all decimal eRT users (via the decimal Launcher) and all users will be required to update to the released version to continue using the software.

Release Notes

For the release notes for each version of the decimal eRT application, please refer to the decimal eRT Version History page.

Release Version Compatibility

The decimal eRT app is tested for version compatibility by .decimal prior to release to customers. However, it is still important for each site to independently test and verify the data integrity of each version prior to release at the site. Specifically, .decimal will test the version compatibility by:

- Adding manual and automatic data upgrades, as appropriate, for changes in the data model. When
 applicable, these changes are required to be sensible to the clinical environment and will be
 documented in the release notes.
- Test the final dose calculations of matching patients between the two app versions to ensure the final doses exactly match (unless the app release notes has been otherwise indicated that the dose calculations have changed).

Prior to releasing a new app version into a site, it is imperative to ensure that the data is compatible between the existing version installed in the clinical environment and the new version that is intended to be installed. This should be tested according to the Clinical Safety Guide for your site.

Testing New Releases

New release versions of the decimal eRT application should be tested prior to clinical deployment using the decimal Launcher Sandbox feature and the decimal eRT Sandbox configuration where the new version can be tested for clinical acceptability according to the Clinical Safety Guide. Sandbox and release versions of applications are managed via the decimal Launcher and decimal Direct app management system. Guides for these features can be found in the decimal Launcher Updating

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Applications guide.

The following procedure shall be followed in order to safely release new versions of an application:

- 1. Perform Data Backup of all clinical patient data.
 - 1. While this step should be unnecessary, it is recommended as a precaution in case problems arise during the version upgrade.
- 2. Review the release notes for the new version and ensure you understand the changes and acknowledge any risks of deployment of the new version to your site.
- 3. Install the release candidate version of the application to the decimal Launcher Sandbox environment and use the decimal eRT Sandbox Testing process to open clinical data in the isolated sandbox mode.
- 4. Open existing patients in the Sandbox environment. You should ensure each of the following for the existing patients and plans in the sandbox testing:
 - 1. The patients and plans all open without errors.
 - 2. The final dose result is the same as the previous version. Note: for unapproved plans the dose results may recompute. For approved plans the dose and device results should be exactly the same.
 - 3. Perform any testing deemed appropriate in regards to the changes outlined in the release notes and required by regulatory guidelines for treatment planning system upgrades.
- 5. Once the release candidate has been thoroughly tested and is ready for release, notify all users at your site of the pending release and set an appropriate date and time for the release (it is generally good practice to stop all active clinical use during the upgrade, so it is best to choose a time outside of normal clinical operating hours). At the designated date/time back up the clinical data (data may have changed since the previous copy was made, so do not skip this step).
 Keeping the latest backup of data is important as it provides the ability to roll back to a working clinical state should the release process fail.
- 6. Using the decimal Launcher Updating Applications guide, release the new version of decimal eRT to your site for the Clinical environment.

Data Duplication or Backup

decimal eRT patient data can be duplicated or backed up by manually copying the file system stored on disk. This will create an exact replicate of the original data used by decimal eRT. This process allows for data backup, release testing, or data manipulation without adversely impacting the original data store.

The Data Backup Recommendations section outlines the recommended frequency for backup of each data storage element used by decimal eRT. Refer to Data Management (Storage and Caching) for an outline of each data storage location to determine the appropriate scope of the data duplication or backup.

Copying Data

The current data storage locations are set in the decimal eRT application settings page. By copying the folders linked from these settings, the application data is fully captured and backed up.

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Linking to New Data Storage

To restore or link to a different data store, open the decimal eRT application settings page and update each setting to the new file storage location.

decimal eRT Patient Data Model

The following page describes the hierarchy of data used to manage patient data records within the decimal eRT treatment planning environment.

There are three main levels for how decimal eRT 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 Courses.
- 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. Course(s)

- 1. A description of the patient's anatomy. Contains a single CT image set and all structure contours (targets and organs at risk) associated with these images. A Course can contain any number of associated Plans.
- 2. Contains the physician's orders for treating this Course and contains information about the prescription and other clinical goals for the Course.

3. **Plan(s)**

- A detailed model of an electron therapy treatment. Most aspects of the patient planning information are stored here (e.g. Beams, Devices, Dose). A Plan will implement all of the Course prescription and physicians will approve a Plan to indicate it is ready to proceed to QA and (if successful) on to actual patient treatment.
- 2. A Plan also contains a QA record (once the plan is approved) that facilitates completion of plan dose QA and device QA.

Hierarchy

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

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| Patient Data Model | | | |
|--------------------|--------------------|---|----------------------|
| | Patient | | |
| | - Patient metadata | a information (name | , demographics, etc) |
| | - Data imported fr | om provided DICOM | files |
| | | Course | |
| | [1 - n] | - Imported DICOM patient model (CT, Structures) | |
| | | - Prescriptions and Clinical Goals | |
| [1] | | | Plan |
| | | | - CT Curves |
| | | | - Points |
| | | [1 - n] | - Treatment Beams |
| | | | - Devices |
| | | | - Dose |
| | | | - QA |

System Requirements

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

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decimal eRT User Guide

Overview

The decimal ElectronRT (eRT) application is used for planning of electron radiation therapy treatments. decimal eRT is an interactive end user application that allows users to design treatment plans and electron beam shaping devices (e.g.: bolus, blocks, and intensity modulators) and order those devices for fabrication by .decimal.

Purpose

The purpose of this document is to provide guidance on the setup, access, and usage of decimal eRT.

Getting Started

Proper use of this software is critical to safe and effective treatment of patients using plans generated by this application. Users are expected to read and understand this complete User Guide including the Instructions for Use, which outlines the general usage principles and limitations of the decimal eRT app. Users must read and understand these instructions before operating the system for clinical use. Refer to each section below for complete details:

Instructions for Use

- Overview and Indications for Use
- User Responsibilities
- Warning
- Intended Use
- User Profile
- Product Features
- Patient Data Model

Precautions

It is the responsibility of those utilizing this application to ensure that all usages of this product relating to patient treatments are performed by trained and qualified personnel only and that such personnel is aware that the quality of any generated treatment plans is highly dependent on the quality and correctness of the input data; therefore if any questions or uncertainties regarding the quality, units, or identification of input data arise, they must be investigated and resolved before the data are used.

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Initial Setup

Once decimal eRT has been purchased, .decimal staff will assist with beam model creation, software installation, and user training. Users will generally be trained at two separate levels, system administrators and end users. System administrators will be setup with appropriate access and tools for managing the software, including both the local resources and user accounts. End users will be primarily trained on the details of generating high-quality treatment plans using the local client portion of the application. Additionally, the medical physics team will be trained and assisted in completing the beam modeling and equipment setup processes, which are explained more fully in the Commissioning Guide (this guide is not available at this time).

Installation

The decimal eRT application is installed via the decimal Launcher client application. Refer to the decimal Launcher user guide for details on using the decimal Launcher.

The main high level requirements for using the decimal Launcher and decimal eRT application are:

- 1. .decimal Direct account credentials
 - 1. This account needs association with a Site ID (.decimal Customer Account number) that has been licensed for use of the decimal eRT application
 - 2. This account needs specific .decimal Permission for accessing the eRT modules
- 2. The decimal Launcher installed

Please refer to the decimal eRT System Requirements page for complete details on hardware and network requirements.

Site Settings and Facility Model

When using the decimal eRT app for the first time users will be required to setup and configure their site facility settings. This includes organization level details (name, report logo, override materials, etc) and specific site details (ordering address, physicians, DICOM export servers, QA options, and machine commissioning).

The Organization Configuration user guide section describes each of the blocks and configuration interfaces.

DICOM Receiver

The decimal ElectronRT application supports importing DICOM patients via a DICOM listener/receiver. Refer to the ElectronRT DICOM Receiver setup guide for instructions for enabling and configuring this method of DICOM patient import into the eRT application.

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Keyboard and Mouse Controls

The decimal eRT app utilizes keyboard shortcuts to help streamline many commonly used functions and display controls. A complete listing of these shortcuts along with a full description of the mouse controls is located at the Keyboard and Mouse Controls page.

Application Usage

The following sections are thorough guides providing complete information about each task within the decimal eRT application.

- Launching decimal eRT
- DICOM Patient Import
- Patient Courses
- Electron Plans
 - Prescription
 - Patient Geometry
 - Points
 - Uniform Thickness Bolus
 - Imaging
 - Density Overrides
 - Electron Beams
 - Electron Block Creation
 - Electron Skin Collimator Creation
 - Electron Bolus Creation
 - Electron Intensity Modulator
 - Electron Beam Normalization
 - Plan Approval
 - Plan Reports
 - Plan QA
 - DICOM Export
- Organization Configuration
- Sandbox Testing
- App Settings

Improper System Usage

When using decimal eRT, as with any complex program, there is the potential for misuse. The decimal eRT app is a radiotherapy treatment planning tool that is intended to be used by experienced and knowledgeable professionals working in the field of radiation therapy.

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Known Application Limitations

Below are listed the known application limitations, defects, or inconsistencies.

General

| ID | Affected Version(s) | Description |
|----|----------------------------------|---|
| 1 | 0.0.1 0.0.2 0.0.3 0.0.4 | decimal eRT does not show the MU value for beams and treatment plans. |
| 2 | AII | Simultaneous record access: If multiple instances of the application have the same treatment plan record opened, changes will be prevented from being pushed to the patient database if the treatment plan is changed first by another user. This will cause the other simultaneous instances to become outdated. Changes to the local application on outdated instances will be blocked from pushing plan changes to the patient database, but the changes may still appear to have happened in the local application. Users will be warned of their changes being blocked by the error: "Plan revision is outdated. Please close and reopen the treatment plan to continue using this plan." |
| 3 | All | Random Application Crashes: • If the local or network disk cache becomes corrupted the application may crash at seemingly random places while calculations are computing. Clearing the local disk cache within the application settings may help resolve unreproducible application crashes during calculations running. |

DICOM Import

| ID | Affected Version(s) | Description |
|----|------------------------|---|
| 1 | All | Closing the application immediately after importing a DICOM patient and before the job 'copy_imported_dicom_files_to_course' completes will cause an incomplete CT Image Set when exporting DICOM later in the application. |
| 2 | 0.9.0+ | Only plan files with a valid bolus in at least one beam will import properly. |

DICOM Export

| ID | Affected Version(s) | Description |
|----|------------------------|---|
| 1 | 0.0.2 | Exporting local DICOM files and providing no export directory will cause the DICOM files to be exported to the local application installation folder. This will cause the decimal Launcher application to invalidate the local eRT install and require a redownload of the application. |

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Beams

| ID | Affected Version(s) | Description |
|----|------------------------|--|
| 1 | | Adding more than one beam with an optimized thickness bolus can sometimes result in the DVH inspection performance being slow. |
| 2 | AII | Optimized Bolus outside shape is generated to the target size and not the block size. So if manual edits are performed on the block that expand the block shape, the bolus extents may be undersized. This can be remedied by increasing the bolus block outer border. |
| 3 | 0.0.3+ | Skin collimator devices may cause interference with fitting inside of the electron bolus when fitting on the patient surface. This is due to sharp corners that result from a rough patient surface contour. |

Plans

| ID | Affected Version(s) | Description |
|----|---------------------|---|
| 1 | All | (Approved Plans) Users should understand that the eRT application stores only user input information and not computed data. However, since machine models and dose calculation algorithms can change over time, certain calculated data and equipment model data that is considered critical to the patient's treatment record is stored with each plan upon approval. This stored data includes: treatment device shapes (e.g. bolus, collimators, intensity modulators), 3D dose fields per beam, and beam model data. However, it should be noted that data derived from these stored results may be recomputed and is therefore subject to change if Approved Plans are loaded in future eRT versions. One such example would be DVH curves. While the dose is stored and will never change for an Approved Plan, the sampling scheme used in DVH calculations can change over time, therefore DVH curves may change even for Approved Plans if such changes are made in the eRT application. Patient-to-applicator collisions, structure volumes, and QA Dose Calculations are additional examples of information that could change in future application versions as this data remains computed, not stored, even for Approved Plans. |
| 2 | 0.0.1 - 0.0.4 | (Unapproved Plans) Unapproved treatment plans created versions earlier than eRT version 0.0.4 will not have the plan prescription filled in (denoted by the error: "Prescription statement not found in plan") resulting in dose not being displayed within the treatment plan displays. Users can resolve this by re-adding the prescription that previously existed in the corresponding Course. |
| 3 | 0.0.1 - 0.7.0 | (Approved Plans) Approved treatment plans created versions earlier than eRT version 0.8.0 that contain a skin collimator will no longer be able to load the approved skin collimator when opening the plan. Users will be required to clone the approved plan and re-approve the plan to allow the skin collimator devices to be exported or ordered. |

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Application Usage and Features

Launching ElectronRT

In order to Launch the decimal ElectronRT app you must use the decimal Launcher to authenticate and open your desired application.

NOTE: You will need your .decmial Direct user Log in.

- 1. Download and install the decimal Launcher.
- 2. Log in with your .decmial credentials.
- 3. Find decimal ElectronRT and download/launch the application.

For further instructions please refer to the decimal Launcher User Guide.

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DICOM Patient Import

In order to begin planning in the decimal ElectronRT App you must first have patient imaging captured and structure geometries defined. This information is brought in the ElectronRT App by importing DICOM CT and Structure Set files.

Note: DICOM patient import will be disabled until the organization configuration has been completed.

Default Import Directory

The default import directory can be set in the app settings by navigating to View → Settings. This directory will always be the default directory when importing a patient. Users can then further refine the import folder as needed starting from this default level.

Importing a New Patient

The ElectronRT application has two methods for importing new DICOM patients: 1) Manually browsing for local files and 2) setting up a DICOM receiver to accept and import DICOM patients. Refer to the sections below for details on each option.

Local File Import

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If you have a set of Ct Images and structures you can import them directly into a new patient through the "Import Patients" menu.



Fig. 1: Import in the Main App Page



Fig. 2: Import Directory Input

The Import DICOM Files option allows you to either browse your computer or copy the path to the folder that contains the CT images and structures you wish to import. The following options are available for browsing for local files:

- Add Folder: Browse for an entire folder of DICOM files to import into a patient
 - Use recursive folder search: This option can be selected prior to adding a folder to reclusively search and add all DICOM files within the selected folder and all sub-folders.
- **Add Files:** Browse for individual DICOM file(s) to import into a patient. Note: this option does not make use of the recursive folder search option.

A list of selected DICOM files for import will be displayed and you can choose to add more files for the selected patient or remove any files as desired.

Refer to the Processing Imports section once files have been selected to import.

DICOM Receiver Imports

Users can install and configure the ElectronRT DICOM Receiver to receive and save patients for seamless importing into the ElectronRT application.

Users can then specify a DICOM Import Monitoring Directory within the Site Configuration's DICOM Settings block that corresponds to the storage_location field set for the ElectronRT DICOM Receiver. Once the receiver and monitoring directory have been setup and configured, any DICOM patients sent to the ElectronRT DICOM Receiver will automatically show up within the Import Patients display as shown in

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figure 3.

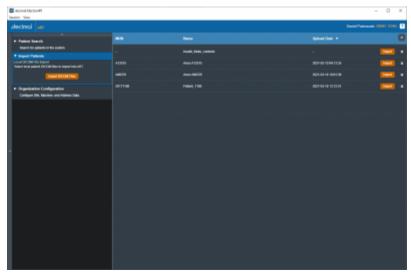


Fig. 3: DICOM Receiver Patients

Each patient received from the ElectronRT DICOM Receiver can be imported or removed from within the eRT Import Patient block.

Refer to the Processing Imports section once a patient has been selected for import.

Processing Imports

Clicking the Import button will start processing the selected files.



Fig. 4: Import Loading screen

If there are no Errors while importing you will be taken to a confirmation page for your import.

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Fig. 5: Import Finalized

If there are errors, please refer to the Common Errors section below for further details.

Importing DICOM Plans

Users have the option to import DICOM Plan files in addition to CT images and structure sets. For now, only electron plans can be imported into the decimal ElectronRT app. When importing a new patient, the DICOM plan file must have the proper UIDs that reference the structure set in order for the plan to be successfully imported. An imported plan will appear under the course of the new patient and will be marked as imported.

Refer to the Imported Plans section for more information on imported plans.

Common Errors

Missing/Undefined External Structure

If the imported DICOM Structure Set does not have a structure flagged as *RT ROI Interpreted Type* (3006,00A4) EXTERNAL you will be directed to specify the external patient structure before the import resumes. The patient external structure must be set to the defining boundary of the patient's outer surface, and not a rind skin structure.

Note: You will be warned if the selected external structure is not the structure with the largest volume. This is to prevent incorrect structure selection. For example, when a 'External' and 'Skin' structure both exist, and the 'Skin' structure is a rind, if the user selects the 'Skin' structure, the warning will state the 'External' structure has a larger volume, since that's the correct representation of the patient structure needed for the ElectronRT App.

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Fig. 6: Missing External Error

The drop down menu will have a list of the structures in the imported set. You will be able to select one as the external for this course then confirm your choice by pressing "Set External".



Fig. 7: Set External Dialog

Structures Skipped During Import

Structures can be skipped during Structure Set import if the structures meet the following criteria:

• Non closed planar (e.g.: points or structures where slices are not fully closed)

Structures that are skipped will be denoted at the end of the DICOM import as shown in figure 8.

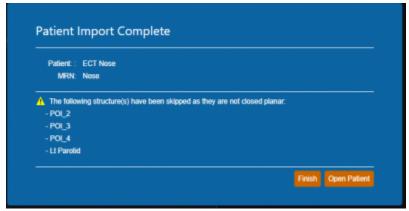


Fig. 8: Import Finalized

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Importing an Existing Patient

If the files you have selected to import coincide with the MRN of a patient that already exists in the database you will receive this error.

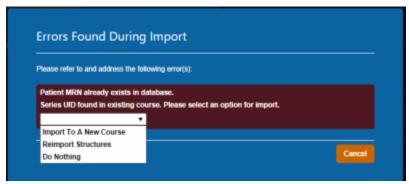


Fig. 9: Existing Patient Error

You have three options provided to resolve the error:

- Import to a New Course
- Re-Import Structures
- Do Nothing

Import to a New Course

Importing to a new course will simply complete the import with the app creating a new course for this patient using the new imported files (note this option will not affect any existing courses or plans for the patient).

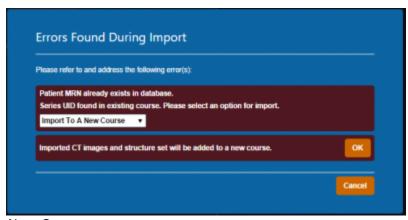


Fig. 10: Importing as a New Course

Re-import Structures

Re-Importing structures can be used if your goal is to update or add structures to an existing patient

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Course.



Fig. 11: Re-Import Structures

After selecting this option, you will be presented with a list of the structures in the import.

For each you may select one of three options:

- **Do not Re-import**: Skips this structure for the re import.
- **Replace existing geometry**: Replaces the existing structure in the current Course with the imported one.
- **Import as new structure**: Imports the structure to the Course as a new structure while not affecting the existing one and allows the user to specify a new name for the new structure. If the structure does not exist currently it creates it as normal.

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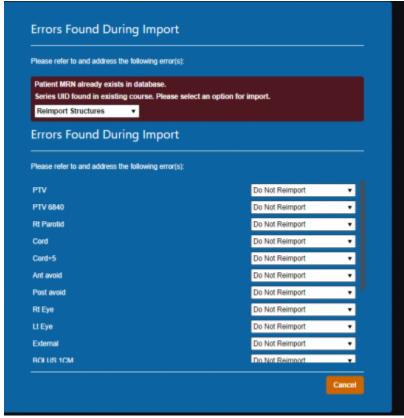


Fig. 12: Re-Importing Structure List

Once you have made your decision for each structure you must select "Re-Import Structures" to finalize your changes.



Fig. 13: Finalize Re-Import

Do Nothing

This is the simplest action, selecting "Do Nothing" will cancel your import and return you to the main menu.

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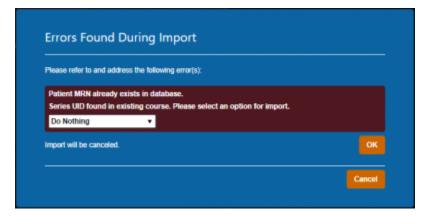


Fig. 14: Do Nothing 2020/06/02 13:32

Patient Courses

Once you have a Patient imported you will need to set up a Course for that patient before being able to create any treatment plans. A Course is used to define the patient's anatomy (e.g.: a single DICOM Structure Set and CT Image Set).

The Course Information settings decided here will be inherited by any plans in this Course and can be edited in the Course UI later to update all non-approved plans within the Course.



Fig. 15: Empty Course Block

Course

In the Course block you can set the following fields:

- **Name**: Initially this label is automatically generated but can be changed as desired.
- **Treatment** Site: This list is taken from your site settings, you are able to add or remove treatment sites from the Site Configurations block. For more information please refer to the Site Settings.
- **External Structure**: The external structure will be automatically determined based on DICOM structure types during import. You are also able to override the initial selection with any other structure in the structure list if desired.
- Physician : This list is taken from your site settings, you are able to add or remove physicians from

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the Site Configurations block. For more information please refer to the Site Settings.



Fig. 16: Course Example

Course Structures

Certain tasks within eRT require structures to be set to a specific type, and their type is set based on the DICOM RT ROI Interpreted Type (3006,00A4) tag during initial patient import. The Course Structures user interface allows users to change the type of each structure within the patient course.

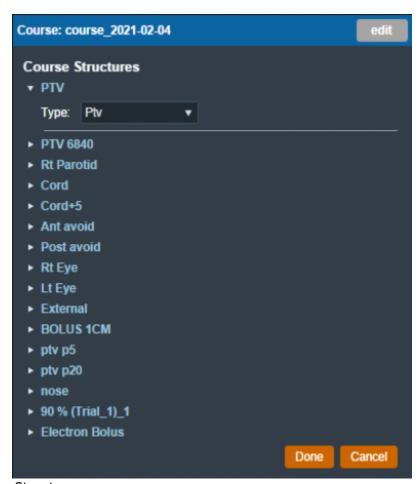


Fig. 17: Editing Course Structures

Note: The RT ROI Interpreted Type (3006,00A4) tag is optional in a DICOM RT Structure Set. As such, the structure type drop down may be empty if no structure type was specified in the imported DICOM files.

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Electron Treatment Plans

Once the patient has a course with a valid prescription, a plan can be created. When adding a new plan to a patient, the user will be prompted to add a name and an optional description for the plan.

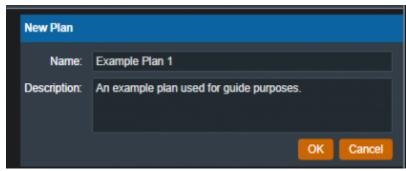


Fig. 18: Creating a Plan

From the Patient Overview, the user can choose to clone an existing plan. As the cloned plan will be a copy of the original plan (except for the plan name and if cloning an approved plan, the clone will be unapproved), the user should name the cloned plan appropriately to avoid confusion.

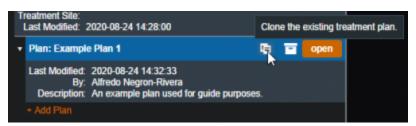


Fig. 19: Cloning a Plan

The user may also choose to make an existing plan inactive. Doing so will remove (hide) the plan from the Patient Overview. The user can view inactive plans and have the option to make them active again if they click the "Show Inactive Plans" check box.

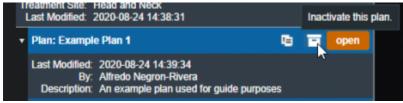


Fig. 20: Making a Plan Inactive

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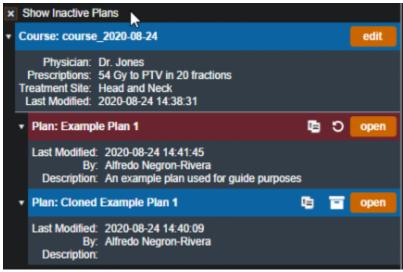


Fig. 21: Viewing Inactive Plans

Approved Plans

Refer to Plan Approval for information on approved plans.

Plan History

The plan history UI exists within the *General Info* block of the plan overview. This interface allows users to view the details of all changes to a treatment plan, view the plan as it was at the time of each revision (as read-only), and make any past revision "active" as the current revision (i.e. restore a plan to match the selected revision).

Refer to figure 22 below for a detailed explanation for each of the Plan History features.

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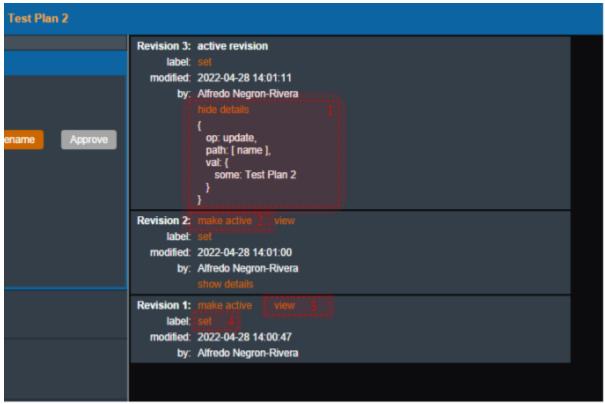


Fig. 22: Plan History

Plan History UI Explained

- [1] **Show/Hide Details**: Provides details of the changes for each revision. Currently the revision comparison shows a textual comparison between the selected revision and the immediately preceding revision.
 - For example: the details shown for Revision #3 tell us that the *Update* operation was performed on the variable *name* to the value *Test Plan2*. Or in other words, the plan's name was updated to 'Test Plan2'.
- [2] **Make Active**: Makes the desired selected revision the current active revision of this plan (i.e. reverts the plan to match this revision).
- [3] **View**: Opens the selected revision for review by the user in a read-only view mode.
- [4] **Set**: Sets the revision label to a user-provided value.

Imported Plans

After a DICOM plan is successfully imported, it will appear under the course containing the structure set that the plan is linked to it. The plan is marked as imported in the Patient Overview.

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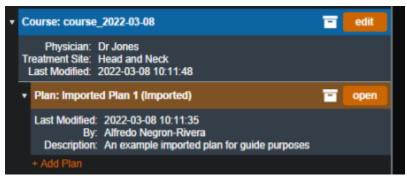


Fig. 23: Imported Plan in Patient Overview

When opening a newly imported plan, the user must first select the CT curve and treatment machine in order to view the imported plan overview.

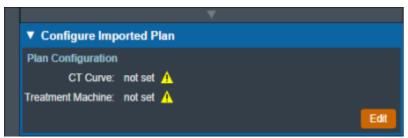


Fig. 24: Imported Plan Configuration

Unlike plans created in the decimal ElectronRT plan, users are limited in what they can do with imported plans. Users cannot add points, density overrides, or edit beams other than adding a Structure as Bolus into an imported plan. Users can approve imported plans and order devices from approved imported plans, but they cannot use QA Tools.

Packing and Exporting Plans

If a plan has to be sent to .decimal for the purpose of troubleshooting, the user is able to pack and export the plan into a zipped folder that can be imported into a different site while still using the data of the original site and machine. The Pack and Export Plan button found after expanding the Plan database info in the General Info block will generate the necessary zipped folder.

The resulting .zip file can be sent to .decimal to unpack and view your patient/plan to reproduce any application issues.

Note: The packed data does potentially contain PHI/PII so should only be sent to .decimal staff using secure file transfer services. The exported files are not encrypted (so that .decimal staff can re-import them), but are a non-human readable, proprietary compressed binary format.

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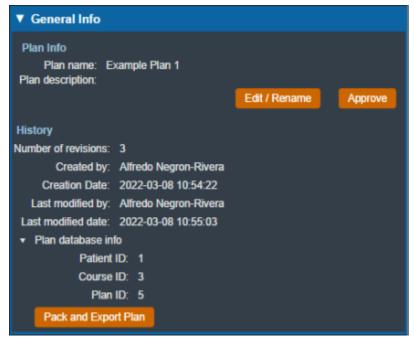


Fig. 25: Pack and Export Plan Option 2020/06/02 13:34

Prescription

You can add multiple prescriptions for different target structures and all of them will be applied to the treatment plan. The plan re-normalization value can be used to scale the final plan level dose.

In the Prescription block you can set the following fields:

- **Fractions**: This is the number of fractions over which the prescription dose will be delivered.
- **Prescriptions**: This is the total prescription dose value in Gy (maximum of 100 Gy) and the target structure for said dose.
 - Note that at this time prescription values do not have an exact specified meaning (e.g. mean, min) as the ElectronRT application only uses these values to scale the relative dose to absolute dose in the UI. In the event of multiple prescriptions, the eRT application will use the first prescription statement to set the 100% relative dose value.
- Plan Re-Normalization : The value used to re-normalize the plan level dose.

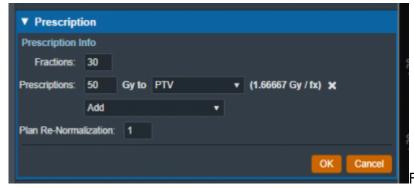


Fig. 26: Prescription Example

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Patient Geometry

The Patient Geometry block allows the user to add points or edit points in the treatment plan. The user may also create uniform thickness boluses that can be used by beams in the plan.

Points

After choosing to add or edit a point, the user will be able to the edit the label, type (POI, localization, or dose reference), color, and description of the point. The geometric position of the point can be determined in one of two ways: as the center of a structure or as an explicit location.

Point Types

The types of points will determine how the point will be used in other features within the application. Below lists the supported point types and how these points are used:

- POI:
 - Used for reference in the Display UI
- Localization:
 - Used for reference in the Display UI
- Dose Reference:
 - Used for reference in the Display UI
 - Dose is shown at the specified point in the Dose Stats display view
 - Will be exported to Plan and Dose QA reports along with the dose/gamma values (see the applicable report second for further details)

Point Creation

The Center option allows the user to set the point's position to the center of a structure selected from the structure set.

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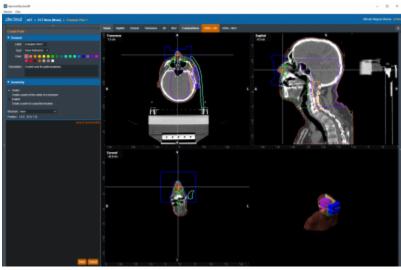


Fig. 27: Creating a Center Point

The Explicit option allows the user to set the XYZ coordinates or simply click on the CT image display to specify the point's position.

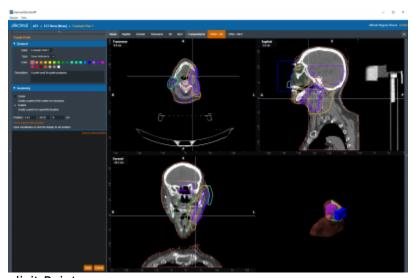


Fig. 28: Creating an Explicit Point

Uniform Thickness Boluses

The user has the option to add or edit uniform thickness boluses within the Patient Geometry block. When creating the bolus, the user can set the thickness and the reference structure. The shape of the bolus will be influenced by the selected structure (e.g. if the bolus will be placed on the patient's skin, the user should select the structure that corresponds to the patient's skin).

After selecting the structure, the user must specify the geometric extents of the bolus in each dimension. The user can either edit the coordinates of the extents by one of two ways:

- 1. **Manual Dimensions:** directly setting the dimension values for the UTB extents box
- 2. **Display Dragging:** drag the sides of the extents box shown in the CT image display.

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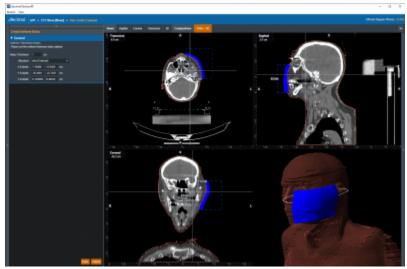


Fig. 29: Creating a Uniform Thickness Bolus 2020/08/12 14:03

Imaging

The Imaging block allows the user to choose or change the HU (Hounsfield Unit) to RSP (Relative Stopping Power) curve to use during the planning process. The user may also specify Density/RSP overrides for existing structures in this block.

CT Curve

The user can select the HU to RSP CT curve from a list of curves that exist within the site configuration. Refer to the Site Configuration Setup for managing the list of curves. If only one CT curve exists in the site configuration, it will be automatically selected when the plan is created. The selected HU to RSP curve will be displayed in the bottom right section of the display UI.



Fig. 30: CT Curve

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Density Overrides

From within the Imaging block users may specify density overrides for existing structures.

The materials allowed for density overrides are pre-defined within the site configuration. Refer to the Organization Settings for adding and managing the density override material list.

Density Override Order

Density overrides are applied in order from the first override in the list to the last override. Any subsequent density overrides applied after existing overrides may change previously overriden densities.

Example of Correct Density Override Order

For example, consider figure 31. The structures HI POLYSTYRENE and PROSTATE both have a density override applied.

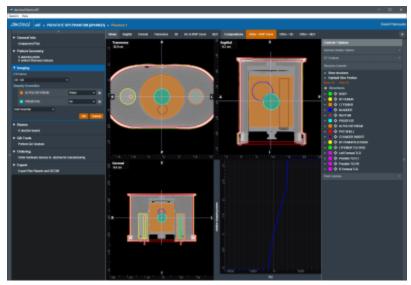


Fig. 31: Override Order

The HI POLYSTYRENE density override will be applied first and all pixels within this structure will be set to the density of 'Water'. Then the PROSTATE structure density override will be applied and all pixels within this structure will be set to the density of 'Air'. The resulting overrides can be seen in figure 32.

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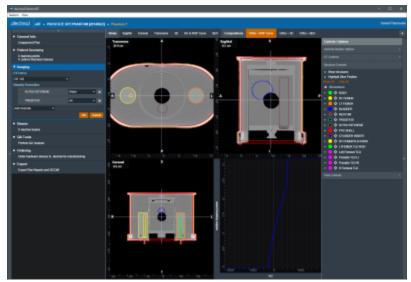


Fig. 32: Override Order

Example of Incorrect Density Override Order

For example, consider figure 33. The structures HI POLYSTYRENE and PROSTATE both have a density override applied.

The PROSTATE density override will be applied first and all pixels within this structure will be set to the density of 'Air'. Then the HI POLYSTYRENE structure density override will be applied and all pixels within this structure will be set to the density of 'Air'. The resulting overrides can be seen in figure 33. Because the larger structure's density overrides were applied last, the smaller contained structure's density overrides were lost.

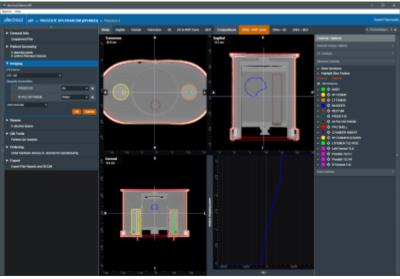


Fig. 33: Incorrect Override Order 2020/06/02 13:36

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Electron Beams

In the Beams block users can manage all the beams, as well as any blocks, boluses, or other devices included with them, included in the plan. In addition, new beams can be created and added to the plan from here.

Note: The Beams block will be disabled if no machine or CT curve exists in the site configuration.

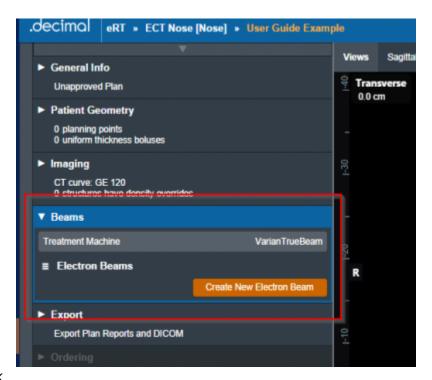


Fig. 34: Beams Block

Managing Existing Beams

The electronRT application will list all beams included in a plan. For each of these existing beams, selecting it will show a summary of the details for that beam. Additionally, as shown below, the user has three options for the selected beam:

- Clone: Create an identical copy of the selected beam and add it to the plan.
- **Edit**: Open the editing dialog to change any editable property of the beam.
- **Delete**: Remove this beam from the plan.

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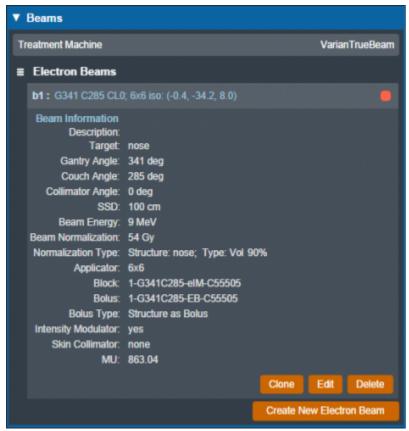


Fig. 35: Existing Beam Example

The editing dialog allows the user to edit any property of the beams that is defined in the "Structure of a Beam" section below. All changes made in this section will be saved to the beam once the user selects "Done".

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Fig. 36: Beam Editing

Creating New Beams

Selecting "Create New Electron Beam" directs the user to a similar section as editing an existing beam with the exception that some blocks are disabled until prior required steps are completed. An in-depth

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explanation of each of these sections is defined in the "Structure of a Beam" section below.

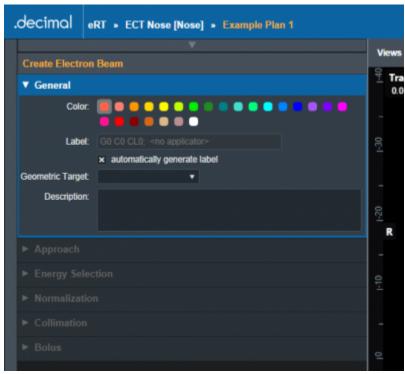


Fig. 37: Creating a New Beam

Structure of a Beam

General

The "General" Section of the Beams block allows the user to set the following fields for the beam:

- **Color**: Sets the color for this beam, this is used for displays, graphs and beam lists in the User Interface.
- **Label**: Sets the Label (name) of the beam. By default, the "automatically generate label" option is enabled for new beams, un-selecting this option allows the user to manually edit the beam label.

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Fig. 38: General Block

- **Geometric Target**: Sets the target structure for this beam. Only "target" type structures will be available for selection in this list. The following criteria must be met for structures to be able to be selected as a beam target:
 - Structures flagged in the imported DICOM RT Structure Set with the following RT ROI Interpreted Type (3006,00A4):
 - CTV
 - GTV
 - PTV
 - CONTROL
 - Structures with the following within their name:
 - "ctv"
 - "gtv"
 - "ptv"
 - "target"
 - Refer to Editing a Course Structure to change a structure type

Once a geometric target has been set, the application will attempt to automatically calculate and set:

- 1. **Beam Approach:** A computed best guess at an orthogonal beam approach. The gantry or couch angles will be snapped to 0 degrees if:
 - 1. The gantry angle is less than 5.0 or greater than 355.0 degrees
 - 2. The couch angle is less than 10.0 or greater than 350.0 degrees
- 2. **Beam Energy:** The minimum commissioned energy with an R90 large enough to reach the deepest portion of the distal surface of the target.
- 3. **Beam Normalization:** If a matching normalization template is found this will automatically be applied.
- 4. **Block Size:** The smallest fitting block size enabled for the selected treatment machine.

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Fig. 39: Geometric Target Options

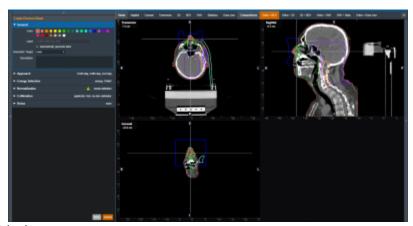


Fig. 40: UI updated with the new target

Once the beam has a color, label, and target the user will be able to move on to the next block in the beam creation if this is a new beam.

Approach

The Approach block is where the user can control the direction and position of the treatment beam. Here the user can set:

- **Gantry Angle**: Sets the Gantry angle for the beam.
- Couch Angle: Sets the Couch angle for the beam.
- Collimator Angle: Sets the Collimator angle for the beam.
- **SSD**: Sets the Source-to-surface distance.
- **Isocenter Shift**: Shifts the beam's isocenter. This shift is within the beam space coordinate system where the SSD is the beam "Z" shift. This can be used to manually shift a beam based on the center of the target.

As the values are set and changed in the "Approach" Block you should see the image of the beam update in the UI.

Note: If the combination of approach settings cause a collision between the applicator and the patient, you will receive a warning and the beam will be unable to be created/saved until the collision is cleared or the warning is specifically overridden.

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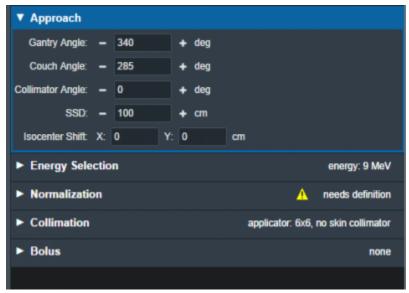


Fig. 41: Approach Block

Energy Selection

In this block the user can select the treatment energy for the beam. Users are able to set:

- **Planning Isodose:** The user can set the planning isodose level (relative dose) for the distal edge of the selected target.
- **Beam Energy:** The user is able to select an energy for this beam. This list of energies is derived from the machine data in the site configuration.



Fig. 42: Energy Selection Block

This block also displays the following values that are calculated and are not editable.

- **Min Energy to Target:** The minimum energy necessary to reach the entire selected target.
- Max PTV Depth (WED): The maximum physical depth (and water equivalent depth) to the distal target surface.
- **R##:** The computed beam range at the Planning Isodose level (range = depth of the point on the PDD at the Planning Isodose for a beam at the selected energy and specified field size).

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Fig. 43: Energy Selection Values

Electron Beam Normalization

In this block the user can specify how the electron beam will be normalized. Absolute dose based normalization can be selected to scale the computed relative dose (%) to absolute (Gy) dose.

If the Course is assigned a treatment site with a beam normalization template and the the selected geometric target is one of the prescription structures, the normalization will be set according to the template in the treatment site. If the the geometric target is not a prescription structure, the absolute dose value must be set by the user. Refer to Editing the Site Settings to set a beam normalization template.

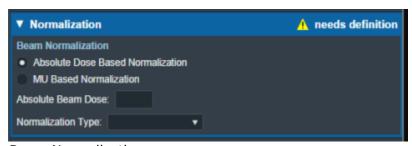


Fig. 44: Absolute Dose Beam Normalization

If MU dose conversion tables exist in the machine selected for the plan, MU based normalization can be selected to scale the relative dose based on a user specified MU value per fraction. In this case, the absolute beam dose value is calculated based on the given MU value per fraction. MU dose conversion data tables can be imported in the Site Configuration Machine Settings.

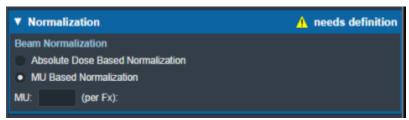


Fig. 44: MU Based Beam Normalization

The eRT application provides the following options for absolute dose based normalization:

• Location: Normalize the dose to a small spherical volume surrounding a specific point.

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- Users are able to specify the sphere's center point and radius.
- The average *Given Dose* within the specified sphere is computed and set to the *Absolute Beam Dose* value when normalizing the beam.
- The normalization sphere will be shown in the sliced views when this location-based normalization option is used.
- **Structure**: Normalize the dose to a structure from the imported DICOM Structure Set. The following structure options are available to normalize dose to a structure:
 - **Min**: The minimum *Given Dose* within the specified structure is found and this value is set to the *Absolute Beam Dose* value.
 - **Mean**: The average *Given Dose* within the specified structure is computed and this value is set to the *Absolute Beam Dose* value.
 - **Vol**: The *Given Dose* covering the specified fraction of the structure is computed and this value is set to the *Absolute Beam Dose* value.
- Isodose: Set a specific Given Dose value to the Absolute Beam Dose value.

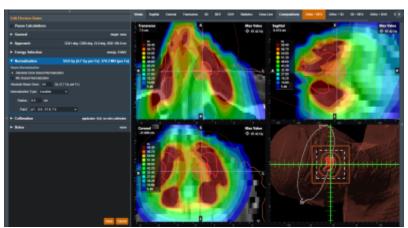


Fig. 46: Location Normalization Sphere

Collimation

Here the user can add or edit an electron block for this beam. The user also has the option to add a skin collimator in addition to an electron block. More details on electron blocks can be found in the Electron Block Creation section below. More details on skin collimator creation can be found in the Skin Collimator Creation section below.

Bolus

Here the user can add or edit a bolus for this beam, more details on bolus creation can be found in the Electron Bolus Creation section below (Intensity Modulators can also be added here).

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Electron Block Creation

Here the user can create and edit Electron Blocks for the selected beam as well as edit values for an existing block.

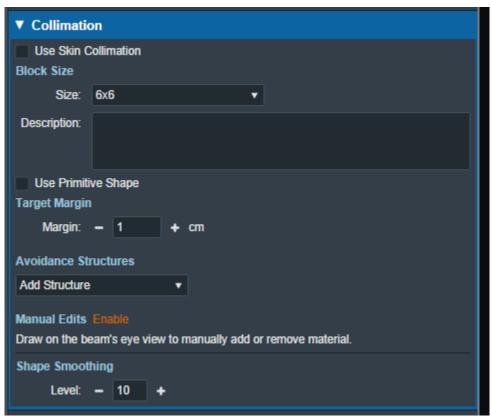


Fig. 47: Electron block controls

Block Size

• **Size:** Select the block size. The list of available block sizes is derived from the list of applicator (cone) sizes available for the selected machine. Applicator sizes can be enabled and disabled from editing the machine data in the site configuration.

Note: When first creating a beam the eRT app will auto calculate the smallest block that will fit the current aperture shape.

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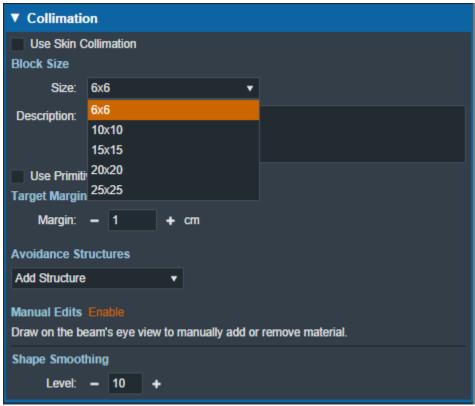


Fig. 48: Block size options

Note Selecting a block size that is too small for the aperture shape will cause an error that will not allow the creation/saving of the beam until an appropriate size is selected.

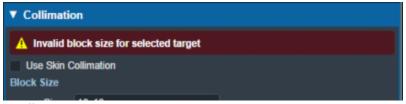


Fig. 49: Block size too small

• **Description:** An optional description for this block used to identify it.

Target Margin

Margin: The value (in cm) of the margin around the target structure as projected to isocenter. A
negative margin can be used to specify a contraction around the beam target while positive values
will cause an expansion. The default block target margin can be configured in the Site
Configuration Machine Settings.

Note: The app will automatically recalculate and display changes to the block as the margin is edited.

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Fig. 50: Block target margin

Primitive Shape

Instead of using the geometric target, the user may use a primitive shape as the base block opening instead. The user can choose the shape (square, circle, rectangle, or oval) and the dimensions at isocenter.

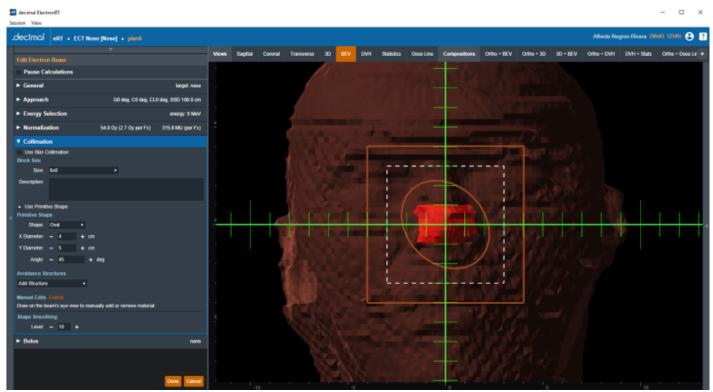


Fig. 51: Primitive shape controls

Avoidance Structures

The user may select one or more structures in the structure list here to add as an avoidance structure. Avoidance structures will decrease the block opening to remove all areas within the projection of the structure.

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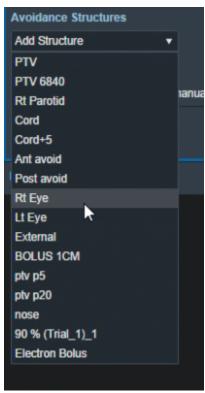


Fig. 52: Avoidance structure selection

Once the structure is selected you will be able to set the values for how it should be avoided. Including:

• **Avoidance Margin:** required, sets the margin of avoidance around the selected structure's projection to the isocenter plane.

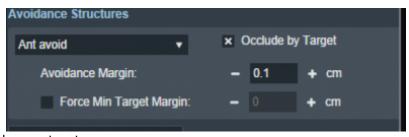


Fig. 53: Selected avoidance structure

• Force min target margin: disabled by default, when enabled it will force a minimum margin around the target taking priority over the settings of the avoidance structure.

For example: As shown below, there is an overlap between the margin set for the avoidance structure and our target structure. Since "force min target margin" is disabled, the avoidance margin has priority over the target.

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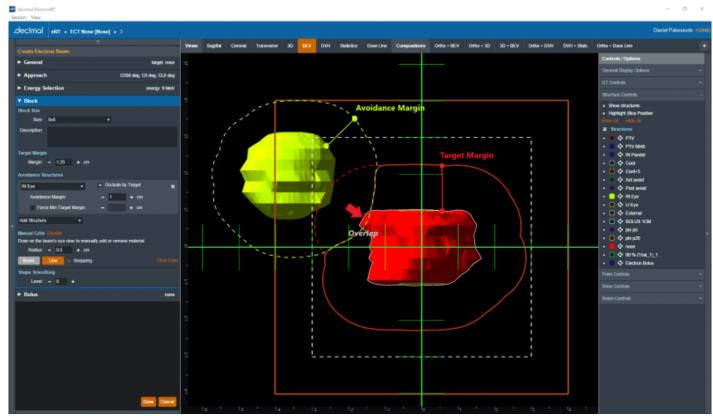


Fig. 54: Force min target margin is off

If the user decides that the target should have priority over the avoidance structure we can enable the "force min target margin" and set a min margin for our target. As you can see below the min margin set takes priority over our avoidance margin and there is no more overlap.

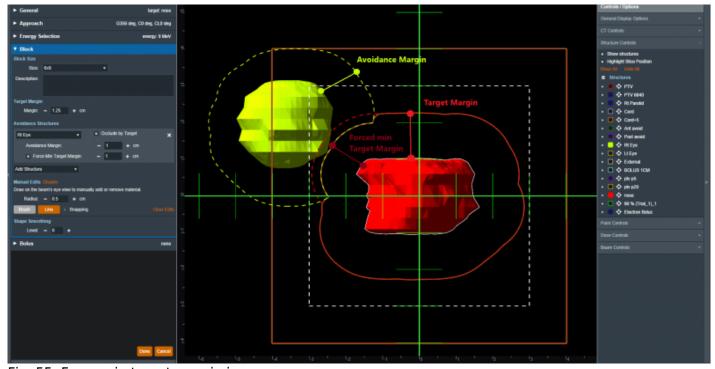
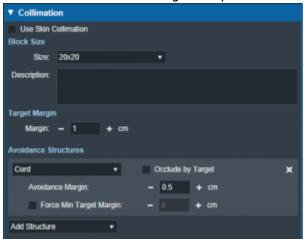


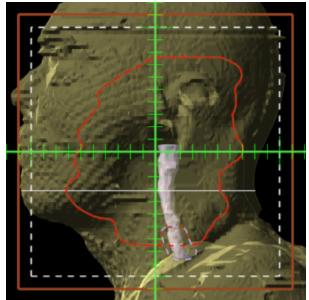
Fig. 55: Force min target margin is on

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• Occlude by target: The user may also choose to occlude the structure by the target or not by using the "Occlude by Target" option. For the following examples we will use the Spinal Cord as it shows a dramatic example of differences of using or not using the "Occlude by Target" option. A 5mm margin was applied to the Cord for the following examples.

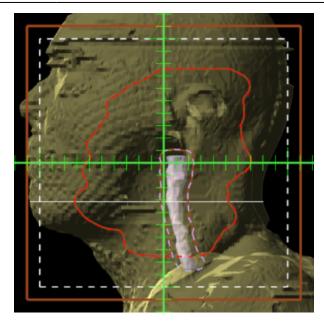


• Checking the "Occlude by Target" option makes the calculations account for the relative depth positions of the target and avoidance structure when determining the area to avoid. More specifically, the visible portion of the target (target volume that is in front of the avoidance structure) will not be blocked by the aperture. Note that just the inferior edge of the Cord is blocked by the aperture as this is the only portion that is visible (not behind the target) and the part of the Cord that is behind the PTV is not blocked.



Unchecking the "Occlude by Target" option makes the calculations ignore the depth order.
 This means the entire avoidance structure will be blocked, regardless of whether it is behind or in front of the target. In this example, the aperture now blocks out all of the Cord.

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Manual Edits

By default manual editing of the block shape it disabled, but a user can elect to enable the ability to manually change the block shape.

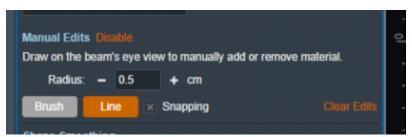


Fig. 56: Enabling manual edits

Once manual editing has been enabled you will see the cursor update to reflect the editing tool. You can choose to edit with the Brush cursor or by drawing straight lines using the Line tool. Both take in the radius that can also be set by the user to alter the size of the editing tool.

Note: Drawing on the "Exterior" of the aperture shape will shrink the shape of the block as can be seen below.

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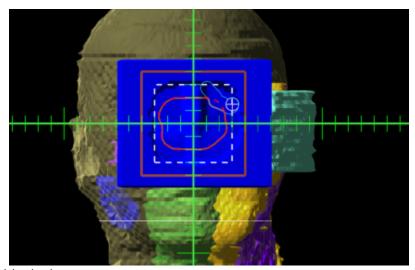


Fig. 57: Shrinking the block shape

Note: Drawing from the "Interior" of the aperture shape will expand the shape of the block as can be seen below.

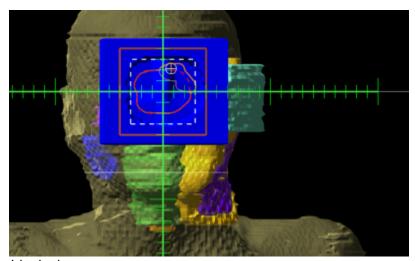


Fig. 58: Expanding the block shape

Shape Smoothing

• **Level:** Sets the level of smoothing applied to the block shape.

Note: The app will automatically recalculate and display changes to the block based on the set smoothing level.

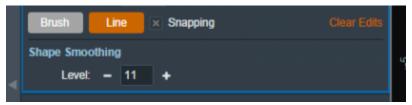


Fig. 59: Setting the smoothing level for the block

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Electron Bolus Creation

An electron bolus is an optional device for each electron treatment beam. A user is able to add an electron bolus to their beams to help improve the dose conformality to the distal target surface. The four options for bolus types in the decimal eRT app are fully defined below.

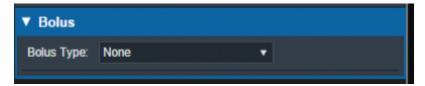


Fig. 60: Beams Block

Optimized Thickness Bolus

The first option a user has for creating a bolus for the selected beam is an optimized thickness bolus. The goal for an optimized bolus is to best fit the specified Planning Isodose level of the computed beam dose to the distal surface of the target structure. The application provides reasonable default parameters for designing such a bolus, so that in most cases, the user can simply click the "Generate Bolus" button and the application will design a suitable bolus automatically. Once the application has finished calculating, the bolus will get added to the beam.

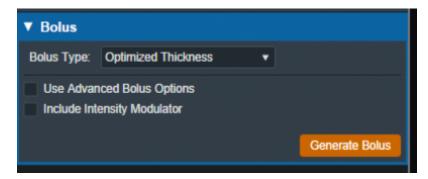


Fig. 61: Beams Block

For complex and challenging plans, a user can also access advanced options to modify an existing bolus or create a new one from scratch.

In the advanced options you can view and manage various operators to augment the design of the bolus. The following operators are available:

Construction Operators (only available when first creating a new bolus):

Automated Marching

This operator constructs the proximal bolus surface using a series of incremental steps. Each
step consists of a small thickness reduction at the optimally selected locations, followed by a
hot spot damping step, in which the slopes of the bolus surface are reduced in areas where

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high dose values are found.

• Geometric Sequence

• This selection performs the following sequence of operators: Create, Smooth, Truncate.

Single shift Sequence

 This selection performs the following sequence of operators: Create, Smooth, Isodose Shift, Smooth, Truncate.

Double Shift Sequence

 This selection performs the following sequence of operators: Create, Smooth, Isodose Shift, Smooth, Isodose Shift, Smooth, Truncate.

Create

This operator constructs the proximal bolus surface by computing the difference between the
physical depth to the distal PTV surface and the depth of the Planning Isodose level along
each ray line of the bolus construction grid (for ray lines not intersecting the PTV, an
extension is performed using the heights of the points that do intersect, which helps ensure
the PTV edges are adequately covered).

Modification Operators (only available after a construction operator has been performed):

Smooth

 This operator performs a Gaussian type smoothing on the current bolus proximal surface, which uses a distance weighted average of the neighboring point heights to compute a new height for each bolus surface point.

Isodose shift

 This operator updates the bolus proximal surface by using the dose results with the current bolus in place to adjust the bolus heights by the difference between the position of the Planning Isodose contour and the position of the distal PTV surface.

Truncate

This operator updates a bolus proximal surface by reducing the height of the bolus in the
region outside the Block Outer Border. The height is reduced to be slightly above the highest
point in the modulated region. It should be mentioned that truncating a bolus may limit the
ability to shift points upward (increase in thickness) when performing manual isodose shift
operators after the truncate.

Specified Shift

• This operator updates a bolus proximal surface by shifting all points (even the region beyond the Block Outer Border) by the specified distance.

Intensity Modulation

This operator manually adds an Intensity Modulator device to the beam. If multiple Intensity
Modulation operators are added in the operator list, then the results of the multiple iterations
of the modulation calculation are combined to produce a single Intensity Modulator device for
the beam.

If an operator is selected from the list the UI will update to show the options for that operation. Once the options have been finalized the user can add the operator to the list which will re-compute the bolus and IM devices for the beam.

Below is an example of adding the automated marching to a new bolus:

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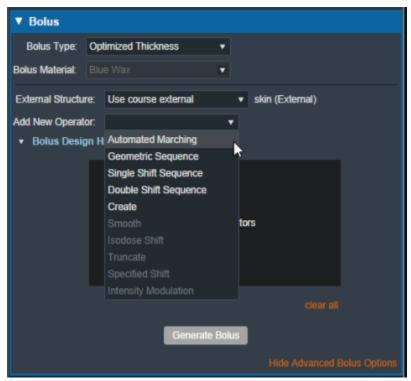


Fig. 62: New bolus operator options

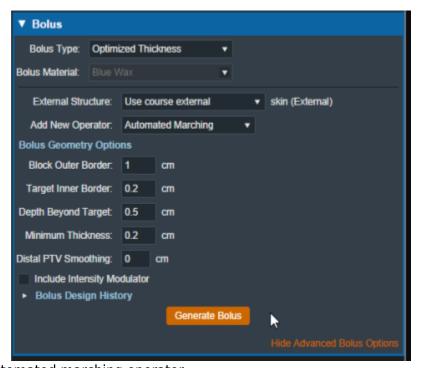


Fig. 63: Adding an automated marching operator

The advanced optimized thickness bolus design parameters allow the user to fine tune the bolus design for specific operators. These options include:

Block Outer Border:

 The distance to extend the bolus surface beyond the block/collimator perpendicular to the CAX.

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• Target Inner Border:

 Specifies the distance to offset the target projection inward when defining the region over which initial construction and smoothing operators act. This is used to reduce the effects that the rapid PTV height changes near the target edges can have on the construction and smoothing operators.

• Depth Beyond Target:

• The beams-eye-view distance past the selected target (along the CAX direction) at which the patient-side surface will be truncated.

Minimum Thickness:

• The minimum allowable thickness of the bolus as measured along a beam aligned rayline.

• Distal PTV Smoothing:

- The smoothing ball radius used to smooth the target structure. A larger radius will result in more smoothing but will also cause a greater deviation of the target from the original structure. Note that setting this value to 0 mm will result in no smoothing for the target structure.
- Smoothing Weight: (Smoothing operator only)
 - The exponential smoothing weight coefficient (smaller value increases smoothing)
- Smoothing Size: (Smoothing operator only)
 - The smoothing distance factor (larger values spread the smoothing range further)
- Additional Thickness: (Specified Shift operator only)
 - The thickness to add to the bolus proximal surface (use a negative value to reduce height)

Additionally by selecting the "Bolus Design History" you can see a list of every step in the bolus design. The last step is removable individually, and there is also the option to clear all steps and start from scratch.



Fig. 64: Bolus design history list

When designing an optimized thickness bolus, you also have the option to select the patient external structure. By default, this is set to the external structure defined in the course.

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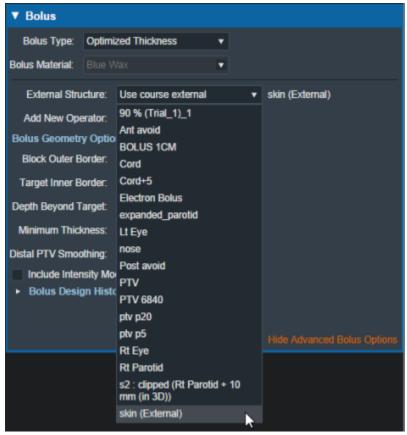


Fig. 65: Bolus external structure selection

If you want to make changes to the beam without having the optimized thickness bolus re-calculate, there is a lock button that prevents the optimized bolus from changing during other beam changes (e.g.: changing the block shape will normally cause the bolus to re-compute). This will lock the bolus design and prevent any changes. If anything in the beam is changed after locking the bolus and the bolus is unlocked then the bolus will be re-computed using the new beam parameters.



Fig. 66: Bolus computation lock

Uniform Thickness Bolus

Uniform Thickness Bolus devices are designed at the plan level, but they must be added to each intended beam individually to ensure the computed dose accounts for the presence of the bolus in the beam path.

decimal, LLC 73/115 decimal ElectronRT User Guide

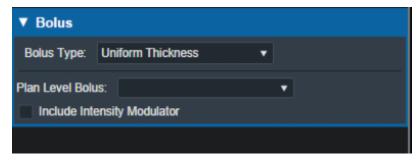


Fig. 67: Beams Block

Structure as Bolus

The user also has the option to use existing plan structure as a bolus. Once this option is selected, the user will be able to choose the structure from the drop down list and the app will set it as a bolus for this beam.

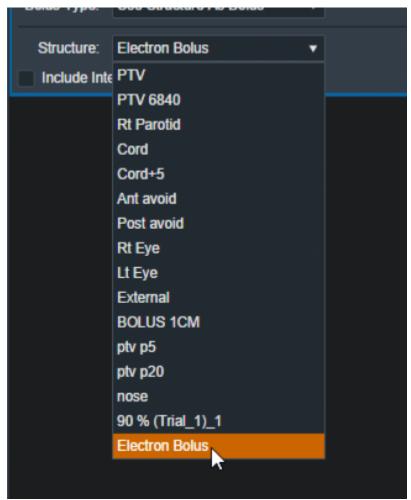


Fig. 68: selecting from the structure list

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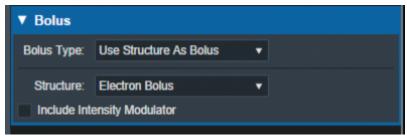


Fig. 69: selecting a Bolus as a structure

Once the structure is selected the bolus will be added to this beam and dose re-calculated.

Note: The bolus is displayed in the BEV for this beam even though the "Electron Bolus" structure is hidden through the right hand side controls. This shows that the displayed bolus is added as a bolus on this beam and not appearing as a structure.

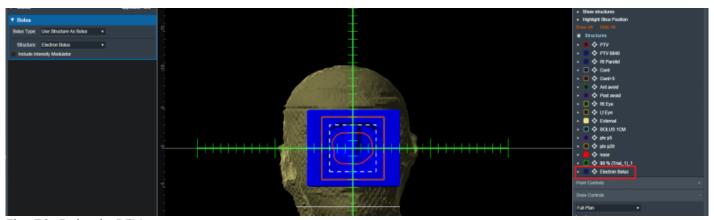


Fig. 70: Bolus in BEV

If you wish to import a bolus that is not currently in your structure list please refer to the DICOM Patient Import section of the user guide for how to re-import a structure set.

Intensity Modulator Device

Additionally if any type of bolus is added to a beam the user is able to also include an Intensity Modulator by selecting the option below any bolus type. The user will then have the option of modifying the dose scaling value applied when calculating the positions and diameters of the intensity modulation pins. The application with calculate the device and display it in the beams UI.

NOTE: In order to add an IMET device the selected beam MUST have a valid bolus.



Circular applicator shapes (e.g.: Siemens 4×4) are not supported for intensity modulators.

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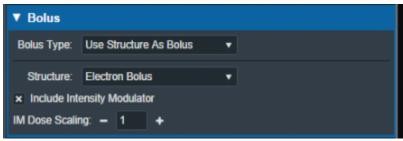


Fig. 71: IM Dose Scaling control

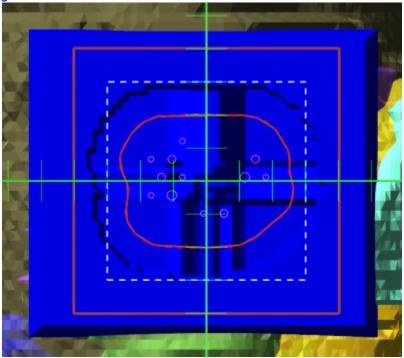


Fig. 71: BEV IMET

As with a bolus, the IM device can be hidden and un-hidden from the display using the beam controls on the right hand size.

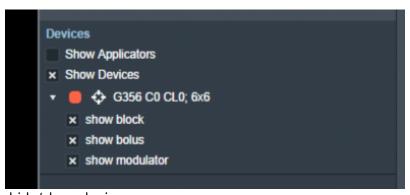


Fig. 73: RHS options to hide/show devices

Users with Elevated Physics level permissions are able to import a user-defined intensity modulation device. The imported device file must be a .csv file with the format: X,Y,Diameter for each pin on a new line. The values must be at the physical block/tray position and the pin diameters must match the supported modulator diameter list.

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An example file is:

im_file_example.csv

```
0.3,-1.55885,0.352
-0.3,1.55885,0.158
```



Fig. 74: Option to import user defined intensity modulator file 2020/06/02 13:38

Skin Collimator Creation

A skin collimator is an optional device for each electron treatment beam. In the Collimation block, the user can create and edit skin collimators for the selected beam as well as edit values for an existing collimator. From within the Electron Beam Task you may add a skin collimator to a beam by clicking the "Use Skin Collimation" checkbox from within the Collimation Block.

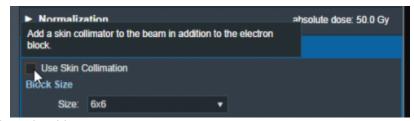


Fig. 75: Skin Collimation Checkbox

A note regarding the use of skin collimation with bolus



Skin collimation can be added to any beam and used with any bolus type, however, only an Optimized Thickness Bolus will automatically conform its shape to correctly account for the presence of a skin collimator. Therefore, caution must be used with all other bolus types as the user must manually review the bolus and skin collimator to ensure there is an appropriate fit (e.g.

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no overlap, interference, or unwanted air gaps) between the skin collimator, bolus, and patient surface.

Collimator Thickness

• **Thickness:** The value (in cm) of the thickness of the skin collimator from the surface of the patient external structure.

Note: The default Thickness value is automatically calculated based on the beam energy. To edit the thickness, click the "edit" control to the right of the thickness value. The app will automatically recalculate and display changes to the skin collimator as the thickness is edited.

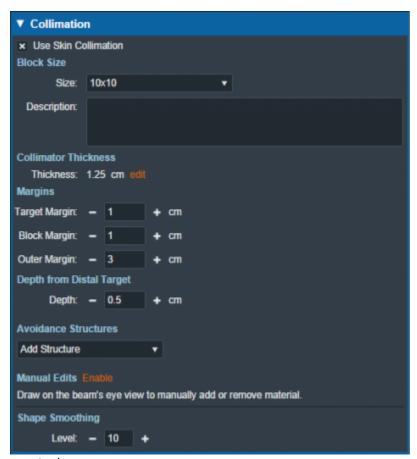


Fig. 76: Skin collimator controls

Margins

- **Target Margin:** The value (in cm) of the margin around the target structure as projected to isocenter. A negative margin can be used to specify a contraction around the beam target while positive values will cause an expansion.
- **Block Margin:** The value (in cm) of the margin between the skin collimator opening shape and the electron block opening shape. When a skin collimator is added to the beam, the block opening

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shape becomes an expansion of the skin collimator opening shape according to the block margin value. Any edits made to the shape of the block opening will be transferred to the skin collimator opening shape when the users chooses to add skin collimation to the beam.

• **Outer Margin:** The value (in cm) of the margin between the skin collimator opening shape and the outer shape of the collimator as projected to isocenter. A negative margin can be used to specify a contraction of the outer skin collimator shape while positive values will cause an expansion.

Note: The app will automatically recalculate and display changes to the skin collimator as the margins are edited.



Fig. 77: Skin collimator margins

Depth from Distal Target

• **Depth:** The value (in cm) of the depth from the distal side of the beam target that is used when calculating the skin collimator 3D shape. Adjusting this value can help improve the skin collimator shape in some situations.

Note: The app will automatically recalculate and display changes to the skin collimator as the depth from distal target is edited.



Fig. 78: Skin collimator depth from distal target

Collimator Avoidance Structures

Using controls that are shared with electron blocks, the user may select one or more structures in the structure list here to add as an Avoidance Structure. Avoidance structures will decrease the skin collimator opening to remove all areas within the projection of the structure. Note that avoidance structures will also affect the shape of the electron block opening as it is an expansion of the skin collimator opening.

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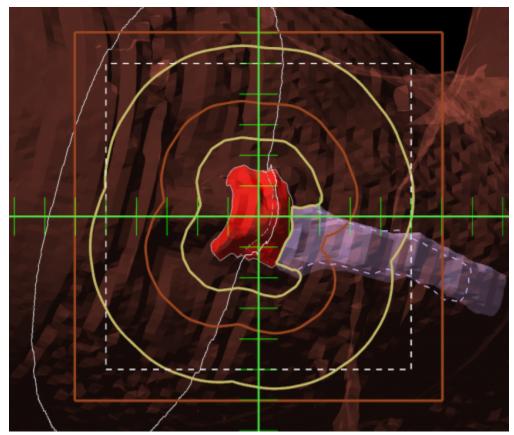


Fig. 79: Skin collimator with avoidance structure

Collimator Manual Edits

By default manual editing of the block shape it disabled, but a user can elect to enable the ability to manually change the skin collimator opening shape in a manner that is identical to Manually Editing the electron block opening shape. Note that manual edits will also affect the shape of the electron block opening as it is an expansion of the skin collimator opening.

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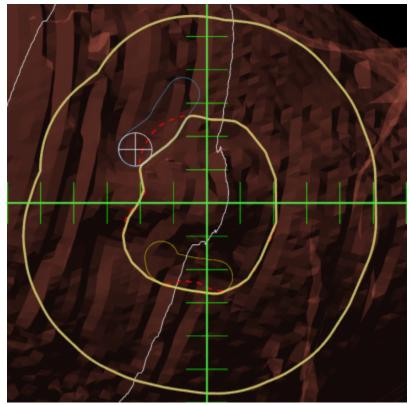


Fig. 56: Skin collimator manual edits

Collimator Shape Smoothing

• **Level:** Sets the level of smoothing applied to the skin collimator opening shape. This does not smooth the patient or beam side surface of the skin collimator.

Note: The app will automatically recalculate and display changes to the skin collimator based on the set smoothing level.

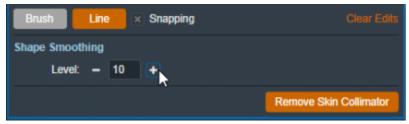


Fig. 81: Setting the smoothing level for the skin collimator 2021/02/12 19:35

Plan Approval

Plan Approval is a mechanism whereby users can "lock" a plan to prevent further edits or changes once it has been reviewed by a qualified radiation therapy professional (typically a licensed Radiation Oncologist). It should also be noted that before users are able to order blocks or boluses in the ElectronRT app, the plan for those parts must be approved by a user with the 'Plan Approval' permission.

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This action ensures parts are not ordered for plans that have not been properly reviewed.

Approved plans differ from unapproved plans in the following ways:

- 1. They are read only and no treatment plan data can be changed
- 2. The plan dose and hardware devices are no longer being recomputed in the UI as during approval those items are saved to the patient disk storage to ensure they never change from how they were viewed at the time of approval.
- 3. The Ordering and Plan QA blocks are enabled

Note, Plans can not be unapproved.



Fig. 82: Plan selection with no approvals

When a user goes to select a plan for a course for their patient, they will be able to tell if the plan is approved or not. Plans that are green are approved while unapproved plans are the standard blue. Approved plans also state the time they were approved and by which user in order to maintain integrity with the plan.

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Fig. 83: Plan selection with an approved plan

Approving a plan

In order to approve a plan a user must simply open the plan they wish to approve and select the "Approve" option inside the General Block.

NOTE: The option will not appear in the following situations:

- The user does not have permission to approve plans
- The plan has no valid beams or there are un-handled errors with the existing beams
- The plan does not have valid dose

In any of these cases the general block will look as such:

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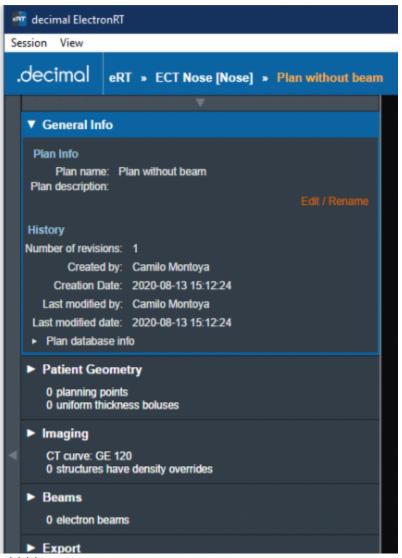


Fig. 84: Approval option hidden

After logging in with an appropriate user and opening a plan that is ready for approval you should see the option available in the general block.

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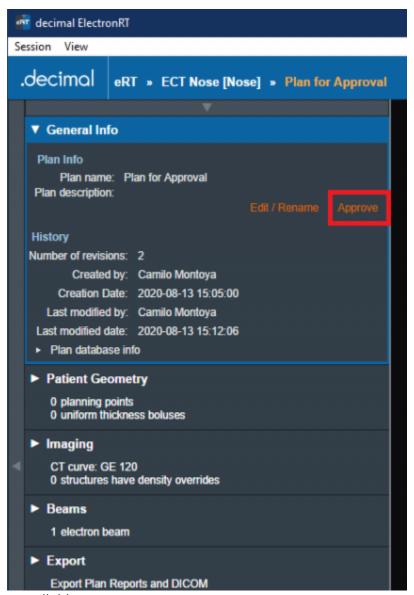


Fig. 85: Approval option available

After selecting to approve a plan a user must confirm their selection. They will also have a final opportunity to change the Name and/or Description for the final plan.

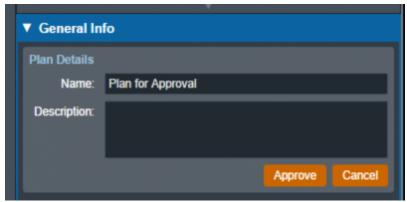


Fig. 86: Import Directory Input

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When that is completed all users on this environment should see the plan as approved (see Figure 2).

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Plan Reports

The ElectronRT App allows PDF export of treatment plan reports. Treatment plan reports include all patient, plan, and beam data and can optionally include screen shots taken in the application.

Note: The Export block will be disabled if no machine or CT curve exists in the site configuration.

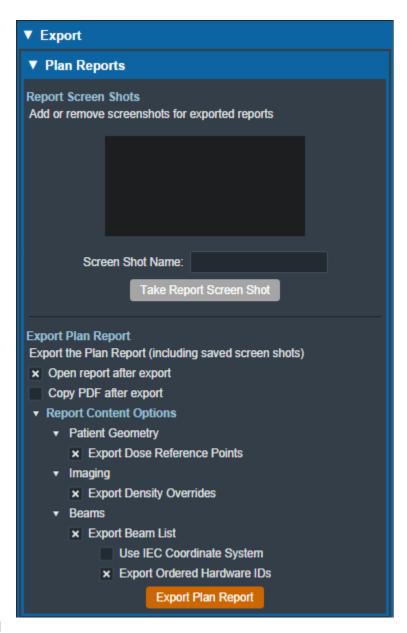


Fig. 87: Plan Report UI

Report Customization

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The ElectronRT App provides options for customizing the exported plan report including: customizing the header logo and setting the different options for details that will appear in the report.

Header Logo

By default, the header logo is set to the logo of the application. The header logo can be optionally overridden by the user in the Organization Configuration block. For more information please refer to the Organization Settings.

The header will be placed as shown in figure 88. The header image is not scaled and is placed on the report at its native size.



Fig. 88: Custom Header

Recommended Size

Since the custom header image is not scaled when placed into the report, it's recommended to use a size that does not interfere with the report contents or reduce the readability of the report.

As such, the recommended image size for a custom header logo is:

Width: 200 to 500 pixelsHeight: 40 to 75 pixels

Larger sized images may still render correctly on the report as long as they fit a standard portrait letter size, but are not recommended since they may impact readability of the report. Images larger than the PDF page may have the image cropped to fit on a single page.

Screen Shots

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Users are able to take screen shots to include on their treatment plan report. Screen shots will include the entire display UI including all CT, Dose, 3D, BEV, and statistics views. Once a screen shot has been captured it will appear on the exported treatment plan report

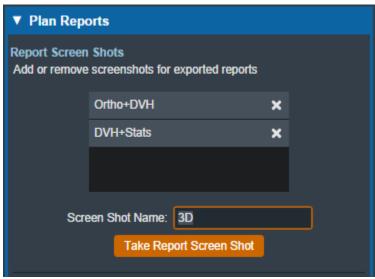


Fig. 89: Report Screenshots

After specifying a name for the screenshot, the application will allow the user to capture the current display and save the screen shot for the plan report.

Managing Screen Shots

Once a screenshot has been captured the following actions can be performed for each screen shot:

- Preview/View: You can view the captured screen shot by selecting the screenshot in the list of saved captures
- **Delete:** You can remove a captured screenshot so that it is no longer exported to the treatment plan report by selecting the 'X' icon next to the screenshot name.

Report Content

By default, plan reports will contain all plan information currently present in the treatment plan. Users can optionally choose to not export specific content to the treatment plan report including: dose reference points, density overrides, beams, or ordered hardware information.

Coordinate System (Equipment & IEC)

By default, the treatment plan report will export beam geometry information in the equipment coordinate system. Users can optionally choose to export beam coordinates using the IEC coordinate system as specified in the Machine Configuration. This option is provided as a checkbox in the Report Content

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Options section.

The selected coordinate system option will be displayed on the treatment plan report as either "Equipment" or "IEC" as shown in the figure 90 below.



Fig. 90: Report Coordinate System

For more information on setting the IEC coordinate systems please refer to the Machine Geometry Settings.

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DICOM Export

The ElectronRT App allows for the export of patient and plan information in the DICOM file format. If the treatment plan is not approved, authorization from a qualified user is required to enable export.

Note: The Export block will be disabled if no machine or CT curve exists in the site configuration.

The user can choose to export the CT Images, RT Structure Set, RT Plan, and RT Dose as DICOM files. There are a few considerations to keep in mind for each DICOM file that is exported from decimal eRT:

• CT Images:

The ElectronRT App allows CT Image export for the convenience of end users only. This
application does not modify CT Images in any way and the exported CT Image files are exact
copies of those imported into the app for the patient course at hand.

• Structure Set:

- Exported RT Structure Sets will be an exact copy of the imported Structure Set data, with a few notable exceptions:
 - The exported RT Structure Set will include override material information for any structures to which the user has applied density overrides in the treatment plan.
 - Structure(s) will be added to the Structure Set for any bolus that are present in beams within the treatment plan.
 - If the user changes the External structure in the Course, that structure will be marked as the External in the exported RT Structure Set.

• RT Dose:

 The computed dose can be exported as a single Plan level RT Dose file as well as separate RT Dose files for each treatment Beam.

For unapproved plans, new UIDs will be generated each time the plan is changed and DICOM files are exported. For approved plans, the DICOM UIDs are fixed and will always be the same each time the

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DICOM file is exported.

Local Export

The ElectronRT App allows the export of DICOM files to a local directory. A default DICOM export directory can be set in the Site Configuration DICOM Settings.

Server Export

The app also allows the export of DICOM files to a DICOM server (AE title). When exporting to a DICOM server, the user can choose to export to a server defined in the Site Configuration DICOM Settings or to a custom server.

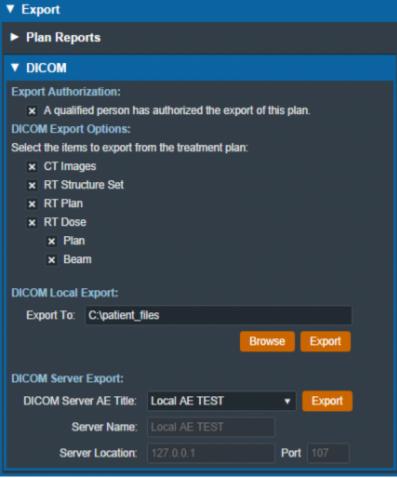
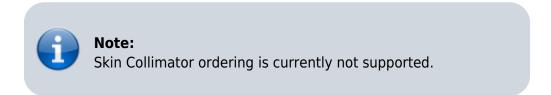


Fig. 91: DICOM Export UI 2020/06/02 13:40

Ordering Devices

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Once a plan has been approved, the user is able to order the devices that were added to the beams in the plan. Ordered devices will be sent to .decimal for manufacturing through decimal Direct via secure HTTPS.



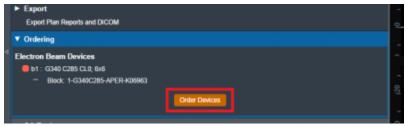


Fig. 92: Part Ordering Example

Select the "order devices" option and all devices will be shown to the user along with the beam in the plan that utilizes said Device. From here users can select which devices they would like to order and move on to the next step.



Fig. 93: Part Selection Example

Once the user has decided which devices to order, the following fields will need to be filled out in order to complete the order.

• **Shipping Address**: The address the devices will be shipped to. The areas listed here can be edited or new ones added from the Organization Configuration block.

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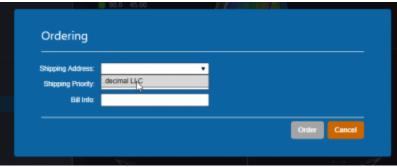


Fig. 94: Ordering Info Example

- **Shipping Priority**: **Standard** (Overnight delivery by end of day) or **Rush** (Overnight delivery before noon).
 - **Note:** Extra charges may apply for Rush delivery.



Fig. 95: Shipping Priority Selection

• **Bill Info**: Any additional PO or specific Billing information to be added to the order. This is an optional field.

Once these fields have been filled the device(s) can be ordered and the user will be provided with a confirmation if the order is completed successfully.

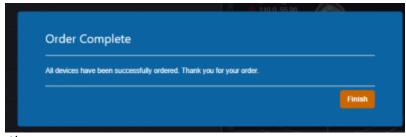


Fig. 96: Order Confirmation

After the order has been placed to decimal Direct the ordered devices will be noted within the Ordering block. Additionally users can view the order report for that device by selecting the highlighted link. This will take the user to the decimal Direct page with the order confirmation for that device.

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Fig. 97: Access Order Report 2020/10/13 21:04

Plan QA

The ElectronRT App includes a set of QA Tools that allow the user to measure each treatment beam dose on a water phantom, compute dose on bolus simulation CT images and compare results, and export QA PDF reports. The QA Tools block is only enabled for approved treatment plans.

Dose QA

The Dose QA block computes and displays the dose for each beam in the treatment plan to a water phantom. For each beam, the user is able to define the SSD and the depth of a measurement plane. This measurement plane will be used to take a cross-sectional sample of the water phantom dose. If a custom water phantom was added to the Site QA Options, the Dose QA block will default to the custom phantom and the user will be able to choose between that and the default phantom. The dimensions of the default water phantom, as well as the default measurement plane depth and dose grid spacing, are defined and editable in the Site QA Options.

After defining the measurement plane depth for at least one beam, the user will be able to click the Export QA Dose Files button to export a QA Dose DICOM file for every measurement plane dose to a local directory. The exported DICOM will include:

- 1. A 1cm thick dose image around the set measurement plane
- 2. [optional] The full 3D water phantom dose if the user has selected the full 3D dose export option

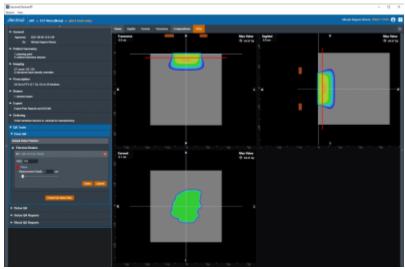


Fig. 98: Dose QA Default Water Phantom

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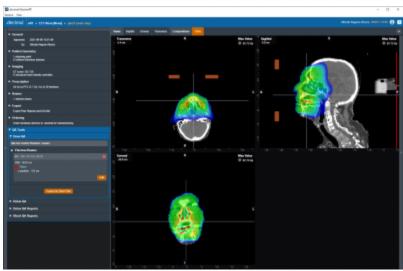


Fig. 99: Dose QA Custom Water Phantom

Bolus QA

The Bolus QA block allows the user to import DICOM CT images and an optional structure set used for bolus QA simulation. The process is very similar to the DICOM Patient Import.

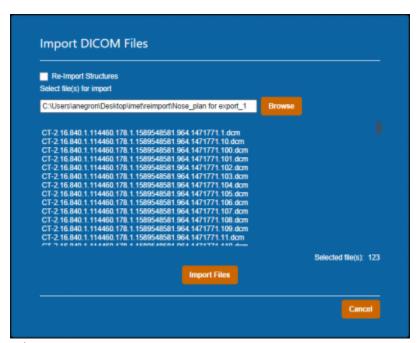


Fig. 100: Bolus QA Import

QA is performed by computing dose on the re-imported CT images (which now contain the actual manufactured bolus) using the same beams as the original treatment plan. The recomputed dose, as well as the original plan dose and a comparison image (using gamma score), are available for display in the UI. The user can edit the Bolus QA block controls to change the gamma parameters as well as shift the isocenter for each beam in the re-computed dose to account for positional shifts in the bolus simulation CT images.

The comparison view shows the three images simultaneously on the corresponding CT images as well as

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a graph displaying the DVHs for the original and re-computed dose images. The user can switch between Transverse, Sagittal, and Coronal for the comparison view in the Bolus QA Display Options in the right side controls.

Users can also set the gamma calculation parameters and required passing rates. This includes:

- Passing Rate (%): The percentage of voxels that must be within tolerance in order for QA to "pass".
- **Spatial Tolerance (cm):** The maximum allowable distance-to-agreement (DTA) value, where DTA is the distance from a point in the original dose field to the nearest point in the re-computed dose field the has the same dose value.
- **Value Tolerance (%):** The maximum allowable dose difference between corresponding points in the original and recomputed dose fields.
- Max Threshold (%): The relative dose value below which dose comparison calculations will no longer be performed

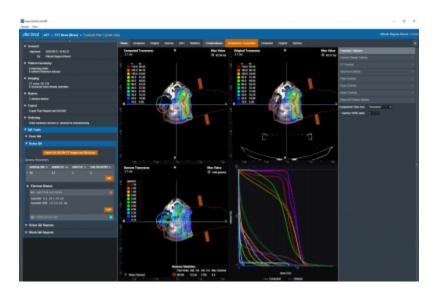


Fig. 101: Bolus QA

Bolus QA Reports

The Bolus QA Reports block allows the user to export PDF reports with data gathered from the Bolus QA block. Just like with Plan Reports, the user can add screenshots of the Bolus QA display UI to the Bolus QA report.

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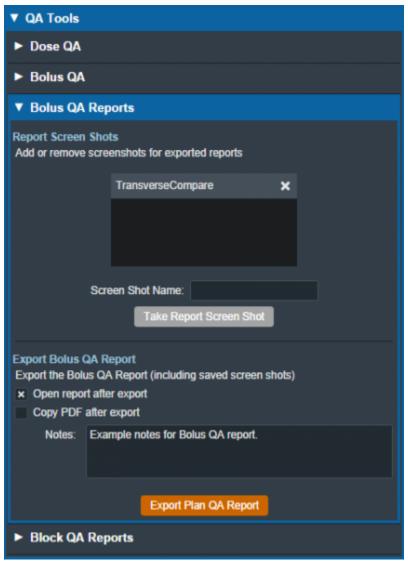
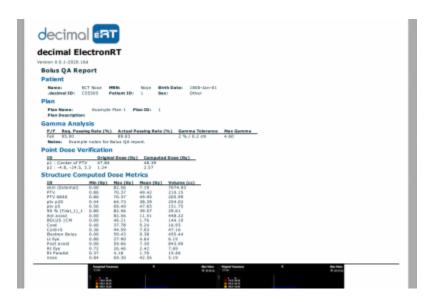


Fig. 102: Bolus QA Reports UI

Bolus QA reports contain basic patient and treatment plan information as well as gamma analysis results, dose reference point data, and structure dose statistics.



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Fig. 103: Bolus QA Report

Block QA Reports

The Block QA Reports block allows the user to export PDF printouts of the electron blocks used in the treatment plan. The user can choose to display each block as a physical (true size) or isocenter projection. There is also a printer-friendly option that removes the color from the block projection (note that for large fields these reports may span multiple pages).

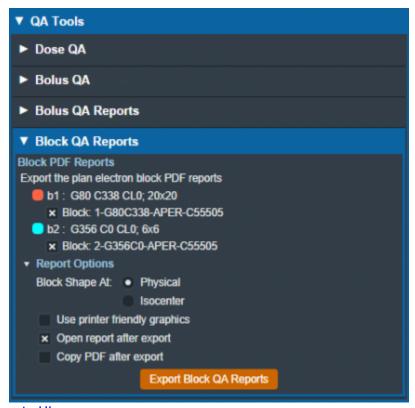


Fig. 104: Block QA Reports UI

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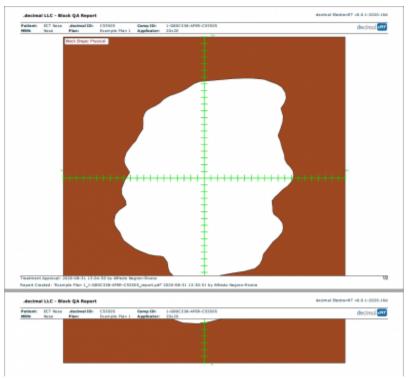


Fig. 105: Block QA Report 2020/06/02 13:39

Organization Configuration

The ElectronRT App allows for users with certain permissions to view and edit organization level configuration settings. The Organization Configuration block is located in the main page of the app and is only visible to users with Physics or higher level permissions.

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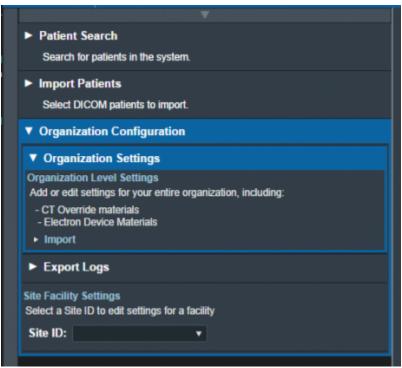


Fig. 106: Organization Configuration UI

Organization Settings

The Organization Settings block allows the user to view and edit settings that affect the entire organization. These settings include organization name, PDF report logo, CT override materials, and electron device materials.

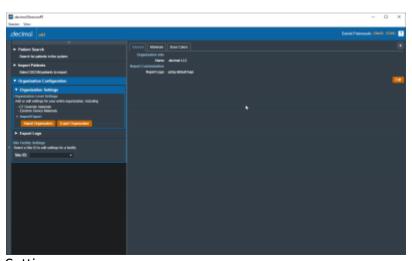


Fig. 107: Organization Settings

While editing the settings in the Organization Configuration block, the UI is changed such that the user cannot click on other sections of the UI until confirming edits with "Done" or canceling edits with "Cancel". Some settings are grouped into tabs, such as the "General" and "Materials" tabs in the Organization Settings.

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Fig. 108: Organization Edit UI

Materials

The Materials definitions allow specifying the device materials and CT override materials. These materials will be usable across the entire organization and all sites.

The units for the materials are as follows:

• **density**: g/cm3

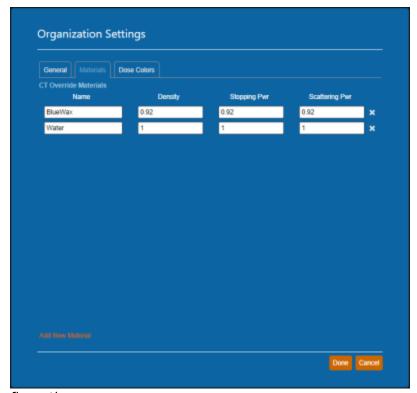


Fig. 109: Materials Configuration

Dose Colors

The Dose Colors definitions allow users to specify the default dose colors and levels when creating new plans. These values will apply to all plans created within the organization across all sites.

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Fig. 110: Dose Colors Configuration

Note: The dose color options set will only be applied to newly created plans. For existing plans select the 'reset to defaults' link within the Dose Controls right hand side user interface to revert to the site level defaults.

Organization Import/Export

The organization import and export user interface allows users to backup, copy, or give their organization data to other individuals as needed. The following details are worth noting about this feature:

- The organization data will not be readable as plain text.
- If applicable, when importing an organization file the organization data will be upgraded to the
 latest version of the data model and automatic upgrades added where appropriate. Refer to the
 release notes for previous versions of the organization since it was last exported for the values of
 these upgrades.
- The application will need to be restarted after successfully importing a new organization.

Export Logs

The Export Logs block allows the user to export a file containing logs of user activity within the app. This .csv file contains data exported from the app database that keeps track of critical user activity, including (but not limited to): opening of patients and plans, plan approvals, report/DICOM exports, and hardware ordering.

Refer to the decimal eRT User Logging guide for details on what actions are logged.

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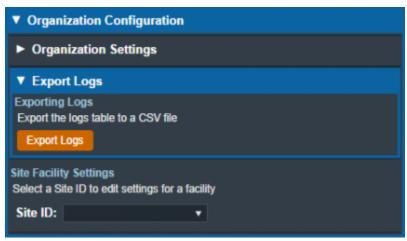


Fig. 111: Export Logs UI

Site Facility Settings

The Site Facility Settings section of the Organization Configuration allows users to view and edit settings for each site in the organization. After selecting a Site ID, the site level settings are divided into five categories: Site Settings, DICOM Settings, CT Curves, QA Options, and Machine Settings.

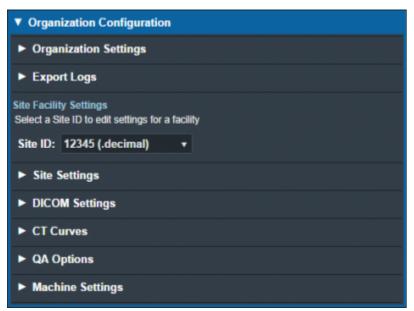


Fig. 112: Site Facility Settings

Site Settings

The Site Settings block allows for the viewing and editing of miscellaneous site level settings including the site address, physicians, and treatment sites. When editing the site address, the UI has an option to set the address to the one assigned to the site in decimal Direct. In order to edit physicians, the user must first click on the physician name on the list of physicians on left side UI and then click on "Edit Physician" on the right side UI (this is also the case with treatment sites). Users can add or remove physicians and treatment sites using the left side UI.

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Fig. 113: Site Settings UI

Plan Defaults / Templates

Beam Normalization

The user can assign a beam normalization template when editing a treatment site. This template will be used to set the normalization during automatic beam calculations for plans in the courses that are assigned to that treatment site.

Note: Refer to Electron Beam Normalization for using and the requirements of the beam normalization template within treatment plans.

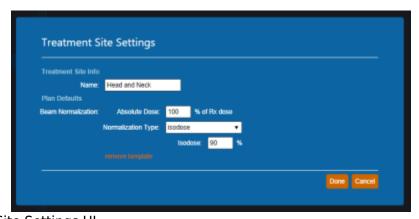


Fig. 114: Treatment Site Settings UI

DICOM Settings

The DICOM Settings block allows the user to view and edit settings related to the export & import of DICOM files. These settings include the default DICOM export directory, a list of DICOM export server AE titles, and the monitoring directory for DICOM Receiver imports.

These settings are applied and available to all users of the selected Site ID for which the settings are present.

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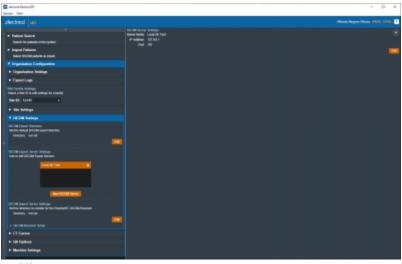


Fig. 115: DICOM Settings UI

| Tig. 113. Dicom Settings of | | |
|--------------------------------------|--|---|
| DICOM Export Directory | | |
| Export Directory | Sets the default export folder when exporting DICOM files to disk. | |
| DICOM Export Server Settings | | |
| Export Export Servers | A list of DICOM AE titles (DICOM Receivers from another system) that the ElectronRT app can export to. | |
| | Server Name: | The name of the DICOM server that will displayed to the user when exporting within the eRT app. |
| | IP Address: | The local network IP address to which DICOM files will be sent by the eRT DICOM sender. |
| | Port: | The local network port on which the DICOM sender should transmit the DICOM files. |
| DICOM Import Server Settings | | |
| DICOM Import Monitoring Directory | Sets the monitoring directory for importing patients received from the ElectronRT DICOM Receiver. | |

CT Curves

The CT Curves block allows for the viewing and editing of CT conversion curves. These curves must contain data for both relative stopping and scattering power. The relative stopping power data for the selected curve is displayed on a graph on the right side UI. When adding a new CT conversion curve, the user can select and import a CSV file that fully defines the curve values. If there are no curves present, the user is able to obtain a sample CT curve file to have an example of the CSV formatting and values. Additionally, each CT conversion curve in the site can be exported as a CSV file.

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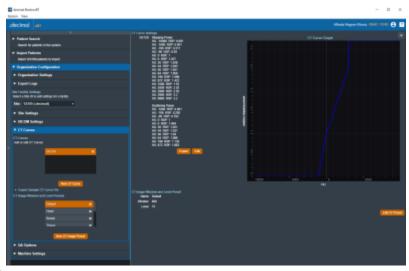


Fig. 116: CT Curves UI

The CT Curves are defined as json as shown in the below example (note: this data is provided as a user guide reference only and should not be used in a commissioned treatment planning system; as such, it does not contain full values of CT curve data):

CT Curve Example

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```
}
```

CT Image Window and Level Presets

The CT Curves block allows for the viewing and editing of CT image window and level value presets. These presets will appear as options in the right side CT Controls for electron plans in the selected site.



Fig. 117: CT Window and Level Preset

QA Options

The QA Options block allows the user to view and edit settings related to Dose QA. The UI allows the import of a CT image set that defines a custom water phantom. The user must define a surface entry point and select a CT curve when importing a custom phantom. Settings used for the default water phantom include the dimensions of the phantom, dose grid spacing, and the default measurement plane depth.

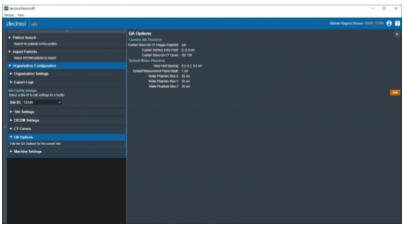


Fig. 118: QA Options UI

Machine Settings

The Machine Settings block allows the user to view, add, clone, and edit machines for the selected site. The machine settings are divided into five tabs: General, Geometry, Applicators, Commissioning, and

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Advanced.

General Machine Settings

The General tab of the Machine Settings block allows for the viewing and/or editing of general machine information such as the machine name, description, serial, type, and physical SAD.

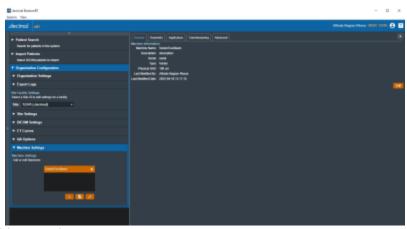


Fig. 119: General Machine Settings UI

Machine Geometry Settings

The Geometry tab of the Machine Settings block allows the user to view and edit Machine (Equipment) coordinate system settings. These settings include the reference gantry angle, reference couch angle, reference collimator angle, and the rotation direction of each axis, relative to IEC 61217 coordinate system.

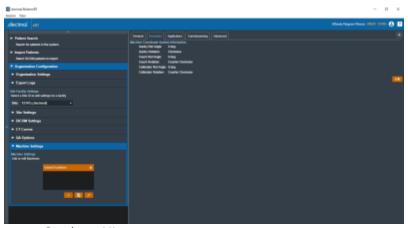


Fig. 120: Machine Geometry Settings UI

Applicator Settings

The Applicators tab of the Machine Settings blocks allows for the viewing and/or editing of applicator and

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beamline device settings. Information regarding blocks, intensity modulators, and applicators of varying sizes are displayed and the user can choose which applicators are available when creating a treatment plan using the current machine. The available applicators are dependent on type of machine (Siemens, Varian, or Elekta) chosen during the creation of a new machine.

While users are able to change the default target margin of the block, it should be noted that users are unable to change manufacturer specific settings (such as physical block size) as these have been preconfigured and validated by .decimal.

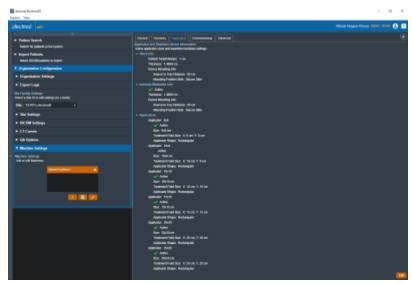


Fig. 121: Applicator Settings UI

Commissioning Data Settings

The Commissioning tab of the Machine Settings block allows the user to view and edit commissioning data by energy. The user can view the nominal energy and R90 values of the current commissioning data or import new commissioning data from a local file. The ElectronRT App currently only has support for commissioning data import from the Pinnacle treatment planning system.

The Commissioning tab also allows the user to import MU dose conversion data tables and display them in the UI. Each MU data file must contain the Output Factor and Air Gap Factor value tables for a given beam energy. The user is able to obtain a sample MU conversion table file to have an example of the CSV formatting and values.

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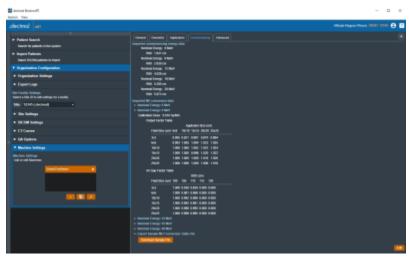


Fig. 122: Commissioning Data Settings UI

Advanced Settings

The Advanced tab of the Machine Settings block allows for the view and editing of advanced machine configuration parameters. These settings include tolerance tables, wedge tray information, blocking tray information, and room imaging parameters. These values are typically not used within the treatment planning process, but are included in DICOM Plan export to meet end user DICOM RT Plan requirements.



Fig. 123: Advanced Machine Settings UI 2020/07/20 15:05

Sandbox Testing

decimal eRT provides a Sandbox isolated testing environment for evaluation of new application versions on non-clinical patient data. This testing mode is recommended to evaluate new release versions of the application prior to distribution to a site and it's users. The physics team at each site should evaluate all new application versions in the Sandbox environment to determine clinical acceptability of the new version following the all industry regulations and professional guidelines as well as the decimal eRT Instructions for Use (including but not limited to: comparison of plan dose, device design, QA, etc). Once the application version is deemed clinically acceptable by testing it in the Sandbox environment, the

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version can then be deployed for use by clinical staff.

Clinical data can be optionally copied into the Sandbox environment (see the Configuring Clinical Data for Sandbox section) or users can choose to start the Sandbox environment with no preexisting data.

The patient data storage and database for the Sandbox environment is completely isolated from the Clinical data. Any changes made within the decimal eRT application while in Sandbox mode will not transfer to the Clinical patient data (and vise versa, updates to Clinical data will not impact Sandbox data).

When in Sandbox mode, users will have full access to all application options as they are available to the user in the Clinical mode.



Note:

The Sandbox feature is accessible only for users with Elevated Physics access or higher.

Configuring Clinical Data for Sandbox

Users have the option to set Clinical patients for use in the Sandbox testing environment. When in the Clinical app privileged users can toggle on the advanced Patient Search option to Configure Sandbox Patients (shown in figure 124 at #1). When this option is toggled on each patient in the filtered display can be set to Use for Sandbox (shown in figure 124 at #2). Patients with this option set will automatically be imported into new Sandbox environments.

If no patients have been configured for use with the Sandbox environment an empty Sandbox environment will be created with only the site configuration.

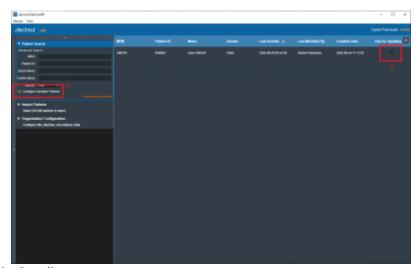


Fig. 124: Use Patient in Sandbox

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Installing the Sandbox Version

Refer to the decimal Launcher Sandbox User Guide for installing an app version to the Sandbox environment.

Running Sandbox Testing

When the decimal eRT application is opened in Sandbox mode the application heading will be Orange and contain a warning that the user is in the Sandbox Testing Environment. This is to ensure there is no confusion to the user about which environment the application is in.



Fig. 125: Sandbox UI Warning

First Time Sandbox Use

The first time the Sandbox environment is created the Clinical site data will be imported into the Sandbox data store. Then any clinical patients flagged for 'Use in Sandbox' will be copied into the sandbox data store. The patients, courses, and plans will be copied to the sandbox environment exactly as they were last modified/approved in the clinical environment.

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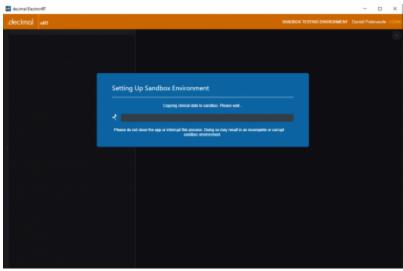


Fig. 126: Sandbox Initial Setup

Consecutive Sandbox Use

The next time decimal eRT in Sandbox mode is used the application will detect an existing sandbox installation and will prompt the user for how to proceed:

1. Use the existing sandbox:

1. The existing sandbox environment will be used exactly how the user last left it

2. Make new sandbox:

- 1. This will completely wipe the existing sandbox environment and reimport the Clinical data following the First Time Sandbox Use process.
- 2. Note: This step can not be undone and all sandbox data will be completely removed. Ensure to manually backup your patient data prior to performing this action if you believe you may need the previous sandbox environment.

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decimal eRT Settings

The following settings are present within the decimal eRT settings UI accessed within the View → Settings menu:

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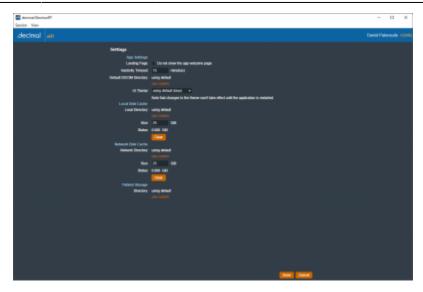


Fig. 127: Settings

App Settings

Landing Page

 Allows the user to specify whether or not to view the application landing page when decimal eRT is opened.

Inactivity Timeout

 Specifies the time out period (in minutes) to automatically log the user out of the application.
 Timeout is based on mouse/keyboard interaction within the user interface. Note: This
 inactivity timeout is different than the user session token received from the decimal
 Launcher.

Default DICOM Directory

 Sets the default DICOM import directory. This directory will be used each time a DICOM import is attempted.

UI Theme

 Set the visual theme of the application (Note: the 'blue' theme is the currently supported theme; a 'dark' theme is available, but is a deprecated theme and not routinely updated at this time).

Local Disk Cache

The local disk cache is where calculation results are stored on the client computer. The recommended storage size for this cache is 25GB.

Users can choose to manually clear the disk cache or let it clear oldest data as the cache fills. Refer to Data Management Storage and Caching for more information.

Network Disk Cache

The network disk cache is where calculation results are stored on a network drive where all users can

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access. If calculation data is not found on the local client cache, the network cache will be checked for the calculation results. The recommended storage size for this cache is 25GB.

Users can choose to manually clear the this cache or let it clear oldest data as the cache fills. Refer to Data Management Storage and Caching for more information.

Patient Storage

The directory for the decimal eRT patient database and file store. The default location is a folder above the application directory installed via the decimal Launcher on the local workstation. Setting this to a shared network resource allows multiple users to share a common patient database.

Refer to Data Management Storage and Caching for more information.

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decimal eRT System Requirements

Purpose

The purpose of this document is to provide an indication of the minimum and recommended system requirements to be able to run the decimal ElectronRT software (including both the decimal Launcher and the decimal eRT user client).

Minimum System Requirements

| 64-bit Windows 10 |
|--|
| Intel Core i7 2.2+ GHz (quad-core) or equivalent processor |
| 16 GB RAM |
| OpenGL 2.0+ compatible graphics card |
| 1920 x 1080 native resolution |
| SSD with 500 MB for application + 10 GB for cache space |
| High Speed internet connection |
| Local user installation (non-admin) |
| |

OpenGL

OpenGL 2.0 or later is required for the application to correctly function (3D views, BEV, block projections, etc). As such, the following scenarios can cause issues with the application:

- **Virtual Machines**: Many virtual machines (e.g.: Hyper-V, VMWare, EC2, etc) may not have a graphics card (GPU). As such the default OpenGL drivers loaded are normally version 1.1, which is not sufficient to run the ElectronRT application.
- **Remote Desktop**: Remote Desktop Protocol (RDP) connections may have trouble loading OpenGL drivers from the host PC, even if the host has a dedicated graphics card (GPU). This seems to be a graphics card/driver issue and is based on the configuration of your host computer. The following article(s) are a few common issues and potential solutions to common OpenGL and RDP problems:
 - GPU Support: NVIDIA's Quadro and GeForce (with Driver Pack 440 or later) are some of the few cards that support OpenGL RDP passthrough. (1),(2).
 - Disabled Group Policy: RDP handles newer versions of OpenGL on Windows 10, but is disabled by default via Group Policy (3).
- **Integrated graphics**: May not have the required OpenGL drivers or dedicated graphical processing capabilities to efficiently use the application.

Recommended System Requirements

| Operating System | 64-bit Windows 10 |
|------------------|-------------------|
|------------------|-------------------|

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| Processor | Dual Intel Xeon(R) 2.4+ GHz (quad-core+) or equivalent processor |
|--------------|--|
| Memory | 32 GB RAM |
| Video | NVIDIA Quadro or equivalent graphics card |
| Display | 2560 x 1440 native resolution |
| Hard Disk | SSD with 500 MB for application + 100 GB for cache space |
| Connectivity | High Speed internet connection >30Mbps |
| Permissions | Local user installation (non-admin) |
| | |

Network Requirements

decimal eRT uses HTTPS communications to our decimal Direct API service to authenticate users, manage application permissions, and order patient hardware. This address and port must be open to passive communication with external addresses from the machine that is running decimal eRT. Note that all communication is initiated from decimal eRT (i.e., there should be no need to forward ports to the decimal eRT workstations), however, you must ensure that the following address be allowed to communicate with the decimal eRT workstation in order for the software to function properly:

| Server URL | direct.dotdecimal.com (64.128.252.104) |
|------------|--|
| Port | 443 (HTTPS) |

In addition, decimal eRT requires the decimal Launcher application for application access and release management. As such, satisfying the network requirements of the decimal Launcher application are also required for using the decimal eRT application.

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