decimal Bolus Designer User Guide

Overview

decimal Bolus Designer is used for designing and editing DICOM structure files to .decimal for manufacturing as a bolus treatment device. The decimal Bolus Designer app allows users to import DICOM files, edit or design the treatment bolus, and place the order to decimal Direct.

Purpose

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

Getting Started

Review each of the sections below for how to get started with the decimal Bolus Designer.

Initial Setup

The decimal Bolus Designer application must be licensed and added to your account by .decimal staff. Please contact .decimal customer support (1-800-255-1613) for access to this application.

Access Control

decimal Bolus Designer 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 Bolus Designer 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 application that prevents unauthorized access, and account sharing should be strictly prohibited.

User Authentication

Users authenticate and launch the decimal Bolus Designer application using the decimal Launcher.

Account Management

decimal Bolus Designer site managers have the ability to add and remove users to their site. When adding a new user an .decimal 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 .decimal password reset process. Removing a user from a site does not delete the user's .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.

User Sessions

When decimal Bolus Designer is launched from the decimal Launcher, the application 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.

Auth0 user credentials are authenticated and validated using the decimal Direct API by decimal Bolus Designer 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 Bolus Designer 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 Bolus Designer application settings. Idle workstation locking at the OS level is also recommended for all workstations with access to decimal Bolus Designer. 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.

Installation

The decimal Bolus Designer 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 Bolus Designer 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 Ordering Tool application

    2. This account needs specific .decimal Permission for accessing the application
2. The decimal Launcher installed

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

Release Management (decimal Launcher)

The decimal Bolus Designer app is installed and launched from the decimal Launcher. The Launcher program provides the following functionality in regards to decimal Ordering Tool:

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 Ordering Tool System Requirements page.

Releasing a new App Version

When a new application version of decimal Bolus Designer 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.

Once a new app version is available, the application will be deployed to the decimal Launcher following the Updating Applications guide. This will immediately push the app update to all decimal Ordering Tool 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 Bolus Designer application, please refer to the decimal Ordering Tool Version History page.

Application Tutorials

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

- Launching decimal Ordering Tool
- Fix Me!

Keyboard and Mouse Controls

The decimal Bolus Designer 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 Data Management

Data Storage

The decimal Bolus Designer 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
3. Network Data Cache	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 application interacts with each data storage element during normal application usage as depicted in figure 1.

Fix Me!

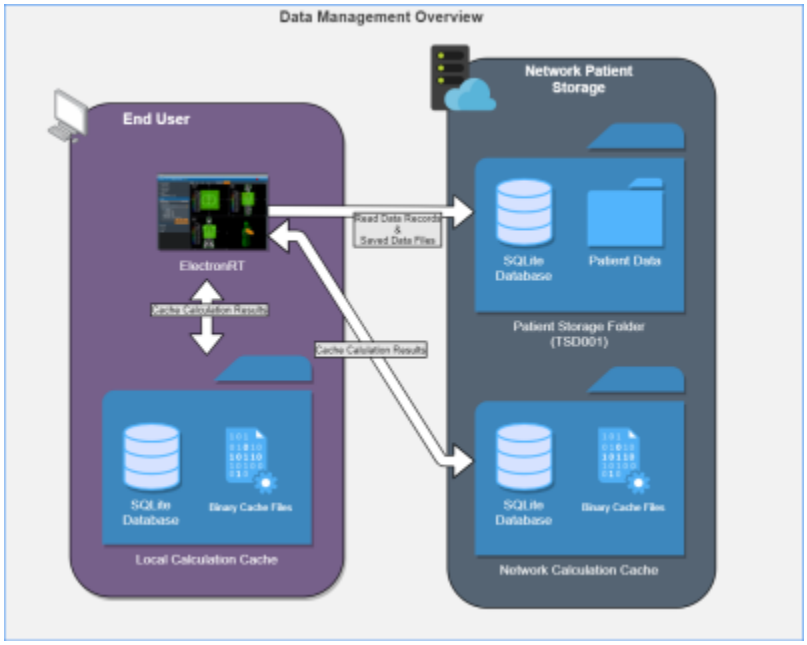

Fig. 1: Data Management Overview

Patient Database & File Storage

The decimal Bolus Designer 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 Fix Me! 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 Fix Me! for further details on how data is prevented from modification and changes.

Network & Local Data Cache

The decimal Bolus Designer 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 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 Bolus Designer is installed the cache locations are set to the following:

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

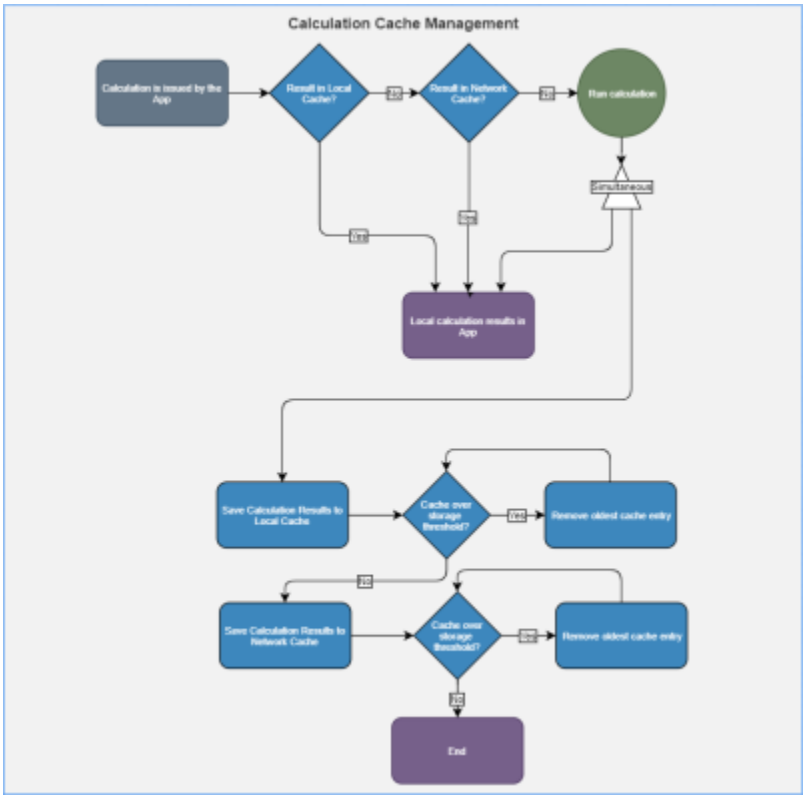

Fig. 2: Data Cache Overview

When the local and/or network cache fills past the set limit within the decimal Bolus Designer 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 locking all critical plan data (devices, etc) is captured in the Patient File Storage.

Clearing the Cache

The local or network cache can be cleared by using the decimal Bolus Designer application settings

Fix Me!.

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 Bolus Designer\cache) and manually remove the entire cache folder
2. Reopen the application and the cache will be rebuilt as the decimal Bolus Designer application is used

Data Integrity

Local Data Storage

As with any software application there is always concern with system and data integrity. decimal Bolus Designer makes use of caching at various system levels to improve performance and mitigate some of these concerns. Refer to Data Management (Storage and Caching) Fix Me! for details on decimal Bolus Designer data caching. While decimal Bolus Designer 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 Bolus Designer 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 Bolus Designer data. The subsequent paragraphs provide supplemental details for each item.

Item	Storage Type	Encryption Type
Patient Database	SQLite Database	AES-256
	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 Bolus Designer data files:** (includes but is not limited to: settings, patients, DICOM 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 Bolus Designer 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 Fix Me! files are a non-human readable, proprietary compressed binary format. 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 Bolus Designer Dicom Conformance Statement Fix Me! for the supported DICOM tags.

Data Backup Recommendations

Since the decimal Bolus Designer 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 Bolus Designer app that should be considered for data backup using the following Data Duplication or Backup Process Fix Me!. Refer to Data Management (Storage and Caching) Fix Me! for a full detailed explanation of each item.

Data	Severity of Data Loss	Recommended Frequency
1. Patient Database	Critical	As frequent as possible (minimum daily)
2. Patient File Storage	Critical	
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 Fix Me! 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 radiation therapy using .decimal requires frequent use of patient-specific devices that are fabricated within our facility, 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 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.

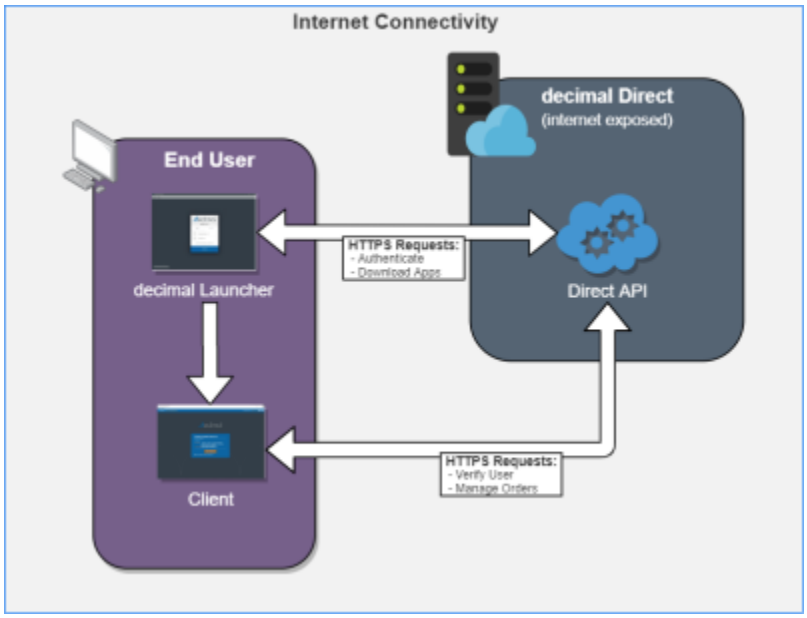

Fig. 3: Internet Data Transfer

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.

Improper System Usage

When using decimal Bolus Designer, as with any complex program, there is the potential for misuse. The decimal Bolus Designer is a radiotherapy medical device ordering 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

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 Ordering Tool System Requirements pages.