decimal 3D System Overview

Purpose:

The purpose of this document is to describe the decimal3D software application including the operating environment and security features available to protect sensitive patient information.

Software Overview:

decimal3D is an FDA cleared medical software device that is accessed on an Apple iPad®. Application release management is handled through the Apple App Store®, which provides assurance of device compatibility and secure application deployment. The decimal3D App allows users to enter standard patient information (name, DOB, MRN, and gender), capture a three dimensional scan of the physician drawn treatment area, digitize the exact shape of the treatment field, and place a beam to complete the design of a patient-specific electron aperture. The decimal3D App then allows the user to order the aperture for fabrication and delivery by .decimal (usually in as little as 24 hours).

Additional details, descriptions, and user information is contained in the official Instructions for Use, which is available online at:

http://apps.dotdecimal.com/doku.php?id=decimal3d:instructions_for_use

General Security Information:

The decimal3D App will contain sensitive patient images and other Protected Health Information (PHI). All such information is stored locally on the host iPad only (all .decimal provided iPads have been configured to disable Apple's iCloud backup service). All Apple devices use disc encryption technology to provide full data encryption at rest, thereby protecting your patient information in the event of loss or theft. Despite this protection, .decimal highly recommends using the "Find My" App provided by Apple to enable rapid recovery, remote locking, and remote wiping capabilities.

It should be noted that all patient critical treatment information must be transferred to the TPS or R&V system for treatment, therefore data stored by decimal3D should not be considered part of the authoritative patient treatment

record. As such, the need to backup or otherwise include redundant copies of the decimal3D patient database is simply not necessary for must institutions.

As decimal3D stores and displays PHI and Patient Identifying Information (PII) on the screen during use, standard precautions should be taken to ensure the iPad locks when idle and is otherwise protected from unintended access (e.g. setting and protecting a strong device passcode or utilizing biometric access). Each decimal3D App maintains a log of all login, access, and order events that can be reviewed if misuse is suspected. Users of the decimal3D software include radiation oncologists and other radiation therapy professionals, such as dosimetrists, therapists, and medical physicists.

Since the primary purpose of using the decimal3D App is to order devices for patients, there is a necessity to transmit device manufacturing parameters and information to .decimal servers so that we can fabricate the custom devices. In order to protect patient privacy, our proprietary order file format contains only the minimal data necessary to manufacture the requested device (a full description of the file format can be found at the end of this document). .decimal values the privacy of patients and security of your 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.** A complete description of the order file content is provided in the final section of this document.
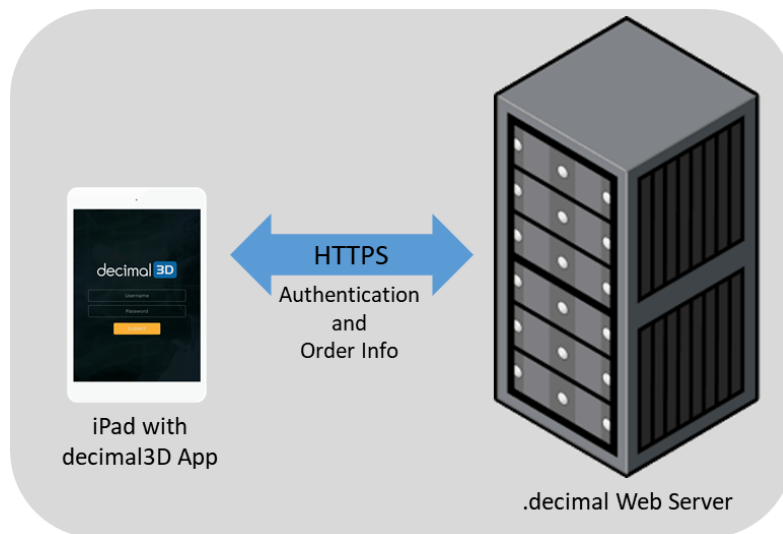

Figure 1: Basic System Diagram

User Accounts:

There are two account types associated with the decimal3D system. First, there is a device level account which is managed by Apple. Software updates and hardware device settings are managed with this account and it should be considered an administrator level account as most end users will not require access to it. .decimal staff will pre-configure each iPad for your clinic, therefore, we will assist in establishing these Apple accounts, if desired, or your Apple ID can be provided to our staff for temporary access (no Apple will be created on your behalf without your expressed consent). The second type of accounts are the .decimal user accounts. Each user of the decimal3D App will require a separate user account that is provided by .decimal. Users can manage their account preferences via our website direct.dotdecimal.com.

Hardware / System Specifications:

Hardware: Apple iPad 7th Generation (128GB, Wi-Fi Only)

Occipital Structure Sensor Mark II for iPad

Operating System: iPadOS 13.X

Connectivity: Active internet connection is required to order (see below)

Network Requirements:

Mention that the iPad must be connected to a wifi network, and brief off line access

decimal3D utilizes port 443 (HTTPS) to communicate with .decimal servers for authentication, order placement, and order status checking. Therefore, an active internet connection is required when performing any of these activities. You must ensure that the following addresses be allowed to communicate with the decimal3D iPads in order for the software to function properly (note that these are secure connections using TLS1.2 protocols):

Port 443:   **direct.dotdecimal.com (64.128.252.104)**
              (used for authentication, ordering, and order status updates)

We understand that Wi-Fi access can sometimes be limited inside the heavily shielded treatment vaults within the radiation therapy department, therefore the decimal3D App has been designed to cache authentication information on the local iPad using Apple's secure Keychain service. This allows user to login

and use the application even when offline. Note that only a few Offline login sessions (the maximum is 10 session at this time) are allowed before the app is locked and the user must again login while connected to the internet. Additionally, since device orders are time sensitive, they must be immediately transmitted to .decimal, therefore, while most App functionality can be used offline, the Ordering process cannot be completed without an active internet connection.

Data included in device order files:

Data	Description
TPS Info	The name and version of the application the generated the order files (decimal3D v#.#)
Patient Info	The anonymized decimal3D generated patient ID
Beam Number	Beam number associated with the device
Beam Description	The beam description associated with this device (supplied by user)
Machine ID	The name of the LINAC used to create this device
Comp ID	The engraving string to be placed on the device (includes the Beam Description and unique ID)
Comp Date	The date and time the file was created
Site ID	The .decimal assigned site ID number (account #)
Contact	The current user's contact information (name, email, and phone number)
Shipping Address	The shipping information entered or auto-populated in the order wizard
Billing PO	The customer provided P.O. number (optional)
Required Delivery	The user selected required delivery (Rush or Standard)
Comp Material	The material of the device (Copper)
Comp Mount	The mounting position of the device
Device Dimensions	The cone size of the electron aperture being ordered
Source Comp	Source-to-aperture distance.
Polyline Points	Series of (X,Y) values in cm that represent the contour that describes the device to be manufactured.