decimal3D Instructions for Use

Overview, Indications for Use, and Intended Use

The primary purpose and intended use of this device is to improve the efficiency of designing patient specific radiotherapy devices through the use of optical (laser) scanning technology. This device will serve as a direct replacement to the current processes for designing such patient-specific radiotherapy devices. One such common current process is for electron therapy clinical setups, which involves hand drawing of the patient-specific aperture shape onto a semi-transparent “template” block, using the treatment light field to verify accuracy against the treatment area that has been outlined directly on a patient by the treating physician. This now flattened and projected aperture shape can then be scanned and digitized allowing for computer controlled fabrication. This new decimal3D device will replace this process by providing a means to accurately scan and digitize the treatment area. After the surface scan is obtained, this device also provides a means for designing and ordering the required devices (e.g. digitization of the field for electron apertures), analogous to the current digitization process in the existing clinical workflow.

This product is not intended to replace CT imaging or other internal imaging modalities and should be used only in cases where a qualified Radiation Oncologist has made appropriate determination of the acceptability of a “clinical set up” approach, independent of any information provided by this application. In other words, the role of this product is to simply ensure efficient and accurate ordering of a patient-specific device from our company, in cases where a licensed Radiation Oncologist has predetermined that such a device and treatment approach is appropriate for the patient at hand. Thus this device’s indications for use include patients with a variety of cancer and disease conditions, which will be treated under the direct supervision and guidance of a radiation oncologist that has prescribed a desired dose of radiation to be delivered to the patient.

User Responsibilities

It is the user's responsibility to test each device ordered through decimal3D for proper function, fit, and clinical acceptability **prior to use on a patient**. The user must also agree to the *Terms and Conditions* as well as the *Processing Agreement* prior to ordering a device for patient use.

Clinical Safety

It is the responsibility that the user performs end-to-end testing prior to the clinical use of decimal3D. The user should follow accepted industry guideline and clinical experience for the end-to-end testing. This testing should be performed by qualified personnel and should ensure (at a minimum) that users are able to scan, digitize, and order an electron block that meets or exceeds the clinical accuracy as compared to the clinic's current process for clinical electron set ups.

It is the responsibility of the facility to ensure that all users of the decimal3D have had training on the decimal3D App and possess the appropriate clinical education and experience to properly use the application.

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.

Prior to the delivery of any treatment on a patient, users are responsible for performing patient specific QA to ensure clinical acceptability of the delivered treatment device. 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 its software or devices.

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

User Profile

The decimal3D App should be used under the guidance of a physician by authorized users such as physicists, certified medical dosimetrists, radiation therapists, and other licensed clinical staff who have been trained by the .decimal staff or by the clinical staff.

Product Features

decimal3D is a medical software accessed on an iPad and managed through the Apple App Store®. decimal3D allows users to enter standard patient information, 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 also allows the user to order the aperture for fabrication and deliver by .decimal.

System Availability and Data Integrity

The decimal3D App is installed on a standard Apple iPad and uses the Structure Sensor by Occipital. These off-the-shelf hardware components are covered by manufacture warranties, which can be

extended to ensure continuous support and service for all components of the decimal3D system. All system data is stored locally on the iPad using secure encryption technology. As this application stores patient protected health information (PHI), clinics should secure the iPad following their internal Mobile Device protection policies to ensure protection of patient data and maintain HIPAA compliance. Remote tracking and lockout software is highly recommended to ensure the iPad data can be locked, deleted, and recovered in the event an iPad is lost or stolen.

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 decimal3D Application:

- All linear dimensions are shown in millimeters (mm)
- All angular dimensions are shown in degrees (deg)
- All date/time values are provided in a *mm/dd/yyyy h:m:s am/pm* format using local time
- All date and time information should match current iOS date and time, including proper use of daylight savings time where appropriate (note: decimal3D will display in am/pm format, while iOS may display in 24 hr format depending on local settings)

Data Validation

Users are responsible for confirming the accuracy of machine data using decimal's p.d App. This data will be used in decimal3D for determining available electron applicator sizes and tray locations. Users should complete a site survey found at https://dotdecimal.com/site-survey/ if they do not have an account with .decimal. .decimal staff will aid users in setting up machines.

Unauthorized Use and Access Control

decimal3D 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. Since all application and data access requires user login credentials, it is important that site administrators implement a strong password policy 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. Please note that in addition to the iPad passcode or biometric access protections, decimal3D requires a separate user-specific login to ensure that all PHI is protected by non-shared access account credentials.

Known Limitations

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

1. Treatment position information (e.g. isocenter, gantry angle, couch angle, collimator angle) is not

available at this time as there is no sufficient link between the scanner coordinate and treatment machine coordinate systems
2. Site information including Machine and Address Settings cannot be edited from decimal3D (these can be edited using .decimal's p.d software available on Windows computers)
3. User passwords cannot be changed within the decimal3D App (please log in to direct.dotdecimal.com to change your password or contact .decimal customer service to request a password reset)

Release Notes

For the release notes for each version of the Planning Application, please refer to decimal3D Version History.

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