decimal3D Instructions for Use

Overview and Indications for Use

The primary purpose of this product is to provide an advanced optical scanning technology using an iPad App that enables the user to capture a three dimensional, full color, dimensionally accurate of the patient and the treatment area drawn by the physician. The user is then able to digitize the treatment area, design the electron aperture as well as place the beam utilizing decimal3D. The decimal3D app also allows the user to order through an interface with the decimal Direct API.

Furthermore, since the accuracy of information 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 before the system is utilized for patient treatment.

User Responsibilities

It is the user's responsibility to test each device ordered through decimal3D 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 implementation of decimal3D. 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 decimal3D have had training on the decimal3D App and possess the appropriate clinical education, experience. This includes, but is not limited to, the application training provided by .decimal staff.

It is recommended that users follow acceptable global standards during the commissioning of the decimal3D. During the clinical set up, the following should be tested to ensure clinical safety prior to treatment:

1. Data access and storage
2. Accuracy of 3D scanning
3. Accuracy of the digitizing
4. Accuracy of the ordering.

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 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 the system.

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

Intended Use

The decimal3D App is an interactive end user application that leverages advanced optical scanning technology to capture a three dimensional, full color, dimensionally accurate rendering of a patient. This rendering can be used for multiple applications including but not limited to digitizing the shape of a physician drawn treatment area and design of the electron aperture to treat this area. The decimal3D includes functionality for the electron aperture to be ordered.

User Profile

The decimal3D should be used the guidance of a physician by authorized users such as physicists, certified medical dosimetrists, radiations therapists, radiologic technologists, nurses and those who have been trained by the .decimal staff or by the clinical staff.

Product Features

decimal3D will handle patient data entry. The user will be able to take a three dimensional scan of the area where the physician has outlined the area to be treated. This scan will be in full color and dimensonally accurate. From this the user can digitize the treatment area, design the electron aperture as well as place the beam. The decimal3D App also allows the user to order the aperture through and interface with the decimal Direct API.

System Availability and Data Integrity

- We need to discuss this

Coordinates and Units of Measure

- should we delete this for the first go round?

Data Validation and Limits

Users are responsible for inputting a lot of data into the Astroid Planning App 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, Astroid does provide some assistance in ensuring data limitations are met by a plan. Machine energy (range) limits, gantry angles, patient support (couch) angles, snout extensions, as well as shifter and aperture sizes and availability are all explicitly limited to user configured levels within the Astroid Planning App controls. Additionally, certain incompatible settings, such as zero thickness rinds and overlapping structure min/max constraints are also explicitly prevented within the Astroid user interface. Despite these many data validation checks, some entries, such as min/max spot MU's are not validated within the Astroid 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. Such warnings should include a statement such as this (or similar): “CAUTION: SOME DATA ELEMENTS USED WERE OUTSIDE NORMAL RANGE”.

Data Displays and Interpretation

decimal3D contains many displays throughout the scanning, digitizing and beam placement process.

Please refer to 

.

Unauthorized Use

The Astroid Planning 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, Astroid has a robust user permissioning scheme, as well as industry standard options for configuring password requirements, as explained at the Thinknode Account Management Settings page. 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.

Access Control

Astroid (Thinknode) administrators have the ability to manage user access, passwords, and “lock” data records to prevent unwanted and unintended modification. Several features have specific access rights that can be configured, including the ability to lock data records, unlock data records, and delete data. By configuring these options, administrators can lock critical data records, such as beam models, equipment information, and other machine/site level data, such that only expressly authorized users can edit these fields. All critical site records such as these should be kept “locked” at all times, and should be unlocked by only be authorized users when expliciting desiring to edit said records (and locking them again after modification is complete). In addition to the practice of locking site data records, users are expected to establish a review process whereby a minimum of two authorized individuals will review all proposed site data changes (including beam models and equipment data) prior to updating the records in Thinknode (please note that at this time, all such records are downloaded, reviewed, and updated through the Thinknode Desktop Client, which is available for download here).

As Astroid is a cloud based application the site administrator will be responsible for the installation of Astroid on to the appropriate workstations. Each user should have an individual log in and password to access the planning app that prevents unauthorized access. Best practices should be followed.

For further information on access management and permission settings please refer to Thinknode IAM Services. The Thinknode services provide two important considerations regarding your clinical data, first, the permission schemes and access control, provide effective control against unintentional and malicious data manipulation and the inherent storage redundancy of the cloud resources provides exception protection against data loss.

Known Limitations

For a list of known system issues and limitations please refer to the following articles for the Planning App and Dosimetry App, respectively.

Planning App Known Limitations

Dosimetry App Known Limitations

Release Notes

For the release notes for each version of the Planning Application, please refer to the .decimal Freshdesk Forum.

.decimal LLC, 121 Central Park Place Sanford, FL. 32771
1-800-255-1613