

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 Astroid Planning App is an interactive end user application that leverages the existing .decimal Astroid Dosimetry App library [FDA 510(k) K150547] of functions (accessed through the Thinknode® cloud services framework) for device creation, dose calculation, optimization, and many other purposes, for the intended use and primary purpose of enabling radiotherapy professionals to efficiently design and analyze proton radiotherapy treatment plans.

User Profile

The Astroid Planning App is a tool to develop radiotherapy treatment plans for delivery using a proton therapy system. 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 proton radiotherapy. Additionally, users are expected to have formal training in general radiotherapy techniques and best practices, proton therapy specific planning techniques, and general principles of patient safety and care. Most users will have college-level training or degrees, as 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.

Product Features

In the most common, primary use case of the software, users will import patient data from existing imaging and contouring software programs, manage physician prescription and intent information, develop a proton treatment plan, and analyze the plan to determine how well it meets the physician's goals. Since the critical treatment planning functions and calculations are handled outside this software application, by a software of known quality and pedigree, the primary and most frequently used functions of this software are the record keeping service (for patient data storage via Thinknode®), user interface controls, and visualization tools. The Astroid Planning App software communicates with other treatment planning systems generally by sending & receiving files in various DICOM RT formats, although the extensive Application Programming Interface (API) of Thinknode® allows users to easily build their own export and import conversion applications. 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 incorrect use of the software, which would be poor or inadequate commissioning of the application (note many other cases of potential misuse have been designed out of the system by limiting allowed user interactions, providing warnings, and preventing unsafe or incompatible operations). This main misuse is mitigated by requiring that users understand that it is their responsibility to perform appropriate quality assurance measurements for every patient plan prior to treatment, which should independently confirm that the treatment plan information displayed within the Astroid Planning App adequately matches the actual, to be delivered, plan. Please note that such testing is a safety and regulatory requirement in most territories.

System Availability and Data Integrity

As with any cloud based application there is always concern with system availability and uptime. Astroid makes use of caching at various system levels to improve performance and mitigate some of these concerns, however, this can never provide 100% assurance and reliability. Since customer has unique needs, specific business agreements will be entered into with each customer as appropriate to detail the reliability guarantees and assurances. Data integrity is generally a less variable concern, as Astroid's cloud storage providers strongly guarantee the highest commercially available data redundancy and integrity limits (approaching 99.999999% per year). Data is transferred to and from the cloud services using secure transfer protocols, that guarantee error-free of transfer using common industry standard techniques (for more details please see the [Thinknode IPC article](#)). While Astroid 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 such a critical feature for application such as this, the Astroid Planning App automatically 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 Thinknode, which provides a log file for

editing of all records and a ensures that patient records are saved securely on an independent medium so they are not lost in the event of a local system failure or crash.

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 Astroid Planning Application:

- The Astroid Planning exclusively uses DICOM coordinate systems for display information (machine based coordinates are NOT available)
- All linear dimensions are shown in millimeters (mm)
- All angular dimensions are shown in degrees (deg)
- All radiation dose quantities will be shown with their corresponding units within the application (e.g. Gy(RBE) or %)
- All date/time values are provided in a *dd/mm/yyyy h:m:s* format using local time on a 24 hour clock
- All date and time notifications in Astroid should match current Windows OS date and time, including proper use of daylight savings time where appropriate (note: Astroid 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 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

Astroid contains many displays throughout the plan creation process. Please refer to [the Astroid Tutorials](#).

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 explicitly 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](#).

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