Planning App Instructions for Use

Overview

The primary purpose of this product is to ... 

User Responsibilities

It is the user's responsibility to commission and test the dose accuracy prior to patient treatment. This general liability on the end users should be understood and communicated to all users and a representative with signatory authority from each facility using Astroid must sign a *User Agreement* stating their understanding and acceptance of this responsibility.

Additionally, a site administrator with signatory authority will be required to sign an *End User License Agreement* on behalf of the facility indicating understanding of the responsibilities for quality and accuracy described herein.

Clinical Safety

It is the responsibility that the user performs end-to-end testing prior to the clinical implementation of Astroid. 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 Astroid treatment planning system have had training on the Astroid product and possess the appropriate clinical education, experience, and (where applicable) licensure to develop clinical treatment plans. This includes, but is not limited to, the application training provided by Astroid staff.

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

1. Geometric relationships of the hardware machine models
2. The dose algorithm
3. Data access and storage
4. Accuracy of the planning dose systems.

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 plan on a patient, users are responsible for performing patient specific QA to ensure clinical acceptability of the delivered dose distribution. Since users are responsible for testing the acceptability of the delivered dose before treatment, Astroid, 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.

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.

Indications for Use

The Astroid Planning App is an interactive end user application that leverages the existing .decimal Astroid Dosimetry App [FDA 510(k) K150547] library 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. Typical indications for use are for the treatment of persons with cancer, over a wide range of potential disease locations. In the most common 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), user interface controls, and visualization tools.

Furthermore, 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.

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.

Product Features

The primary … (don't forgot to include correct and incorrect system usage here) 

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 IEC 61217 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 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 (note: Astroid will display in 24 hour format, while Windows may display in am/pm depending on local settings)

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 here FIMX (thinknode link). 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.

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

Launcher

- placeholder VEP-001 Test 9 #4

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.

Astroid Patient Data Model

The following page describes the hierarchy of data used to manage patient data records within the Astroid planning environment.

Hierarchy

- **Patient**
  - **Course**
    - Prescriptions & Clinical Goals
    - Directive Structure List
    - **Patient Model**
      - Imaging Data
      - Structure Data
        - Active Variant
        - Variant List
      - **Plans**

- RSP Data
- Structures & Points
- Calculation Grid
- Treatment Room
- Beams
  - Snout
  - Devices & Spot Options
  - DRRs
- Fraction Groups
  - Target
  - Constraint
  - Targets (1 or more)
    - Constraint (1 or more)
    - Beamset (1 or more)
      - Beams (1 or more)
- Constraints
- Objectives
- Dose Results

Descriptions

- **Patient**:
  - A person receiving medical treatment. A Patient record contains basic personal information and demographics, as well as any number of treatment Courses.
  - This is where the patient name (prefix, given name, middle name, family name, suffix), medical record number (MRN#), sex (male, female, other, any) and date of birth (month, day, year) are stored.
- **Course**:
  - A prescribed regimen to be followed to treat a specific disease occurrence for a specific period of time. A Course will contain the physician's Intent and Directive information
  - The user will label the Course of treatment and specify the physician of record. The user has the option of adding a description of the course of treatment.
  - The intent captures the physician's purpose for this Course of radiation treatment. An Intent contains information about any protocols this patient is under, as well information regarding the disease site, body system, and body part (for both templating and billing purposes). An Intent can contain any number of Directives (although it's uncommon to have more than one). The user will define the type of treatment (curative, palliative, or prophylactic), as well as the treatment site at this level. A narrative of what the physician desires to achieve as a result of the course is also saved here.
  - The directive is the physician's orders for treating this Course. A Directive contains information about the prescription and other clinical goals for the Course.
  - A Course also contains any number of Patient Models.
- **Patient Model**:
  - A description of the patient's anatomy. Contains a single CT image set and all contour variants (targets and organs at risk) associated with these images. A Patient Models can contain any number of associated Plans.

- **Variant**:
  - A specific model of a target, OAR, or other structure. A physician may provide an initial target contour and a treatment plan generated using this information. The physician may later (using the same CT image set) provide a revised target contour. Rather than import this revision as a new structure or override the original, you may specify this new contour as a variant of the original. Each contour may have only a single “active” variant and the plan will automatically update based on the selection of the active variant. However, in some cases it is not desirable to update the plan, so the user may also choose to lock the plan and simply recompute DVH and other volume based statistics based on the new active variant geometry. In either case, variants can be used to streamline workflows and prevent accidental misuse of out-dated contours.

- **Plan**:
  - A detailed model of a proton therapy treatment. Most aspects of the patient planning information are stored here (e.g. Beams, Fraction Groups, Optimization Information, and Dose Results). A Plan will specify the portion of the Prescription it should meet and physicians will publish (approve) a Plan to indicate it is ready to proceed to QA and (if successful) on to actual patient treatment. There should be only one “published” Plan per Prescription.

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