Instructions for Use

Overview

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.

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: - Geometric relationships of the hardware machine models - The dose algorithm - Data access and storage - Accuracy of the planning dose systems.

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.

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.

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 [0,1,...,N]
        - Intent [0,1,...,N]
            - Directive [0,1,...,N]
                - Prescriptions
                - Clinical Goals
                - Directive Structure List [0,1,...,N]
                - Directive Point List [0,1,...,N]
                - Patient Model [0,1,...,N]
                    - Imaging Data
                    - Structure Data [0,1,...,N]
                        - Active Variant
                        - Variant List [0,1,...,N]
                    - Plans [0,1,...,N]
                        - RSP Data
                        - Points [0,1,...,N]
                        - Structures [0,1,...,N]
                        - Calculation Grid
                        - Treatment Room
                        - Beams [1,...,N]
                            - Snout
                            - Devices & Spot Options
                            - DRRs
                        - Fraction Groups [1,...,N]

        - Target
        - Constraint [0,1,...,N]
        - Targets [1,...,N]
            - Constraint [0,1,...,N]
            - Beamset [1,...,N]
                - Constraint [0,1,...,N]
                - Beam [1,...,N]
    - Constraints [0,1,...,N]
    - Objectives [0,1,...,N]
    - 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.