Dosimetry App Instructions for Use

Overview

The primary purpose of this product is to provide a library of efficient and easily accessible proton dosimetry functions which can serve as the foundational tools for developing higher level radiation treatment planning and analysis software programs. The Dosimetry App is not intended to be an interactive end-user application; instead it will serve as a source of tested and validated calculation functions which software developers can utilize in other end-user applications. The astroid Dosimetry App provides access to these calculation functions through thinknode® which is accessible over the internet and performs all calculations in a cloud based environment. The Dosimetry App exposes three primary types of functions: dose calculation functions (DCF), design task functions (DTF), and radiotherapy support functions (RSF). DCFs provide fast and accurate SOBP and PBS dose calculation results. The DTF are specific device design and/or optimization functions that provide a means of generating dose-based proton device/plan designs. The RSF are lower level utility functions (many of which are used in the other two types) that are common to most all radiation treatment planning systems.

The intended use for this application is to aid software developers in implementing programs that contain functionality similar to radiation treatment planning systems (TPS), including programs designed to provide independent secondary checks of other TPS results. Therefore typical indications for use are for planning or analyzing proton radiation therapy treatments for cancer patients with a wide range of disease locations. This is the context in which this application was developed and it was within this scope of use that the system was tested and cleared for sale by the FDA.

Warning

Since this application is intended to be used primarily by other software developers in a possible wide range of TPS-like applications, the foreseeable misuses are difficult to predict. However, the most likely source of misuse will be simply due to misunderstanding by developers of the input and output data values and formats of the various exposed functions. Therefore it is critical that all developers read these Instructions for Use 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.

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

User Profile

As stated, this application is not intended to be a direct end-user facing program; therefore it will not be used by the average medical dosimetrist for day-to-day planning needs. Rather, the application will be used by experienced computer programmers, researchers, and physicists that contain a strong working knowledge of proton radiation therapy and general treatment planning processes. Within the clinical

setting it is expected that these types of users will develop in-house systems or other commercial applications that utilize the functions provided by this product. While the DCF and DTF have been cleared for clinical use, this does not remove the need for these experienced and educated users to provide final testing and approval of their derived programs before releasing to clinical staff. Since the results from any calculation performed by this product are only as good as the provided inputs, special care must be taken by developers to ensure proper inputs are designed, constructed, and verified for their particular application and clinical setup. This burden can never be removed from the user of the astroid dosimetry app and this is a primary reason why a strong working knowledge of proton radiation therapy and computer programming are required to utilize this product within a clinical setting. The astroid Proton Dosimetry Commissioning Guide is provided to help guide developers along the right path for developing inputs, commissioning their machines, and adequately testing any derived applications. With this resource and a solid understanding of treatment planning system use, commissioning, and QA, developers will be able to create stable and accurate programs that meet their unique clinical and/or research needs.

User Testing 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, accuracy, and security described herein.

Clinical Safety

It is the responsibility of the user to perform 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.

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Derived Applications

Any derived applications built using and upon the astroid Dosimetry App must be independently tested and validated prior to being released or utilized in a clinical environment. The 510(k) for the astroid Dosimetry App has no transference to any derived applications, and any such programs must have their own premarket 510(k) approval.

Product Features

The primary function type provided by the astroid Dosimetry App were explained above, however, some additional details of the features of these functions are provided within this section, so that potential users can become more familiar with the product before delving fully into the complete User Guides and training materials.

Function Access and Data Storage

The primary role of the Dosimetry App is to expose access to various calculation functions and results through a pre-defined Application Programming Interface. Access to the Dosimetry App is internet-based and data access and storage is secure, permission based, and does not contain any patient PHI.

Proton Dose Calculations

The most critical feature of the Dosimetry App is the fact that it provides direct access to clinically-tested proton dose calculation functions for both PBS and SOBP fields. In general, each dose calculation function computes scalar dose values to a set of points distributed in three-dimensional space. The proton dose calculation functions allow for inclusion of standard beam limiting devices (apertures) and devices that are used downstream of beam limiting devices, such as range compensators and range shifters. Dose calculations are made machine specific by proper commissioning of the Proton Treatment Delivery Machine Model described below. Dose calculations incorporate patient specific anatomy information as described by the corresponding section below.

Proton Aperture Designs

The Dosimetry App provides access to functions which produce apertures suitable for proton therapy treatment. Inclusion of machinability through the specification of a minimum milling tool radius is applied to all aperture designs. Aperture shape design also accounts for the position of the device within the beamline and scales the device shape based on a dual source projection scheme to properly account for the physics of certain proton delivery machines. Aperture construction parameters are flexible enough to allow for creation of successful designs for any arbitrarily shaped fields, especially for match and patch field planning.

Proton Range Compensator Designs

The Dosimetry App provides access to functions which produce range compensators suitable for proton therapy treatment. Variable thickness smooth milled range compensators can be designed via standard and novel computational algorithms using a surface representation that inherently produces fully machinable device profiles. As with any radiation technique there are certain inherent limitations in the physics of SOBP fields, therefore it is important to provide tools for designing devices based not only on user specified constraints, but also to provide options for adjusting devices beyond their initial construction phase; this facilitates design of devices that meet a clinician’s needs, even when typical constraints cannot be properly specified or readily achieved. Therefore this application provides not only standard geometric (ray traced) design options, but also dose-based device optimizations as well as localized smoothing, setting, and shifting options. Range compensators can be designed to deliver dose to a specific set of target structures while also properly conforming the dose based on the presence of existing dose from other (patch) fields.

Patient Specific Model

The data modeling component of the Dosimetry App is essential in that it provides a set of defined standard data types and formats that will be used for interaction through the API. While the API itself specifies the available functions, function arguments, and argument types, it is this data modeling component that specifically defines the details of the various argument data types. In order for the dose calculation functions to incorporate patient specific data, data models for the following types are

included: beam geometries, patient CT images and structures, proton devices, and dose calculation point distributions.

Proton Treatment Delivery Machine Model

The current state of proton delivery machines is such that two major modes of delivery are utilized: spread-out Bragg peak (SOBP) and pencil-beam scanning (PBS). Each such mode requires various machine parameters to be defined which facilitate the proper modeling of the dose delivered by a beam. Providing a means for users to specify the parameters necessary to configure their system is therefore an important concern so that the dose calculation algorithms can provide proper results for users of a variety of proton machine vendors. The proton treatment machine model provides user configurable parameters that allow dose calculation results to be commissioned to a variety of proton machine types, especially IBA and Mevion machines.

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