decimal3D User Guide

Overview

The primary purpose and intended use of this device is to improve the efficiency of designing patient specific radiotherapy devices through the use of optical (laser) scanning technology. This device will serve as a direct replacement to the current processes for designing such patient-specific radiotherapy devices. One such common current process is for electron therapy clinical setups, which involves hand drawing of the patient-specific aperture shape onto a semi-transparent “template” block, using the treatment light field to verify accuracy against the treatment area that has been outlined directly on a patient by the treating physician. This now flattened and projected aperture shape can then be scanned and digitized allowing for computer controlled fabrication. This new decimal3D device will replace this process by providing a means to accurately scan and digitize the treatment area. After the surface scan is obtained, this device also provides a means for designing and ordering the required devices (e.g. digitization of the field for electron apertures), analogous to the current digitization process in the existing clinical workflow.

This product is not intended to replace CT imaging or other internal imaging modalities and should be used only in cases where a qualified Radiation Oncologist has made appropriate determination of the acceptability of a “clinical set up” approach, independent of any information provided by this application. In other words, the role of this product is to simply ensure efficient and accurate ordering of a patient-specific device from our company, in cases where a licensed Radiation Oncologist has predetermined that such a device and treatment approach is appropriate for the patient at hand. Thus this device’s indications for use include patients with a variety of cancer and disease conditions, which will be treated under the direct supervision and guidance of a radiation oncologist that has prescribed a desired dose of radiation to be delivered to the patient.

Purpose

The purpose of this document is to provide guidance on the setup, access, and usage of the decimal3D App.

Getting Started

Proper use of this software is critical to safe and effective treatment of patients using devices generated by this application. Users are expected to read and understand this complete User Guide including the Instructions for Use, which outlines the general usage principles and limitations of the decimal3D App. Users must read and understand these instructions before operating the system for clinical use. Refer to each section below for complete details:

- **Instructions for Use**

Precautions

It is the responsibility of those utilizing this application to ensure all that all usages of this product relating to patient treatments are performed by trained and qualified personnel only and that such personnel is aware that the quality of any generated treatment plans is highly dependent on the quality and correctness of the input data; therefore if any questions or uncertainties exist regarding the quality, units, or identification of input data arise, they must be investigated and resolved before the data are used.

Initial Setup

Once decimal3D has been purchased users are responsible for confirming the accuracy of machine data using decimal's p.d App. This data will be used in decimal3D for determining available electron applicator sizes and tray locations. Users should complete a site survey found at https://dotdecimal.com/site-survey/ if they do not have an account with .decimal. .decimal staff will aid users in setting up machines. .decimal staff will train users in the use of decimal3D.

Installation

The decimal3D App is installed on a standard Apple iPad and uses the Structure Sensor by Occipital. decimal3D is a medical software managed through the Apple App Store®.

Tutorials

The following task descriptions are thorough guides providing complete information about each task within the Astroid Planning Application.

System Usage

Improper System Usage

When using the decimal3D, as with any complex program, there is the potential for misuse. The decimal3D App should be used under the guidance of a physician by authorized users such as physicists, certified medical dosimetrists, radiation therapists, and other licensed clinical staff who have been trained by the .decimal staff or by the clinical staff.

Known Application Limitations

Below are listed the known application limitations, defects, or inconsistencies.

1. Treatment position information (e.g. isocenter, gantry angle, couch angle, collimator angle) is not available at this time as there is no sufficient link between the scanner coordinate and treatment machine coordinate systems
2. Site information including Machine and Address Settings cannot be edited from decimal3D (these can be edited using .decimal's p.d software available on Windows computers)
3. User passwords cannot be changed within the decimal3D App (please log in to direct.dotdecimal.com to change your password or contact .decimal customer service to request a password reset)

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