

decimal3D Instructions for Use

Overview and Indications for Use

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, under the direct supervision and guidance of a radiation oncologist that has prescribed a desired dose of radiation to be delivered to the patient.

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 decimal3D App is an interactive end user application that leverages advanced optical scanning technology to capture a three dimensional, full color, dimensionally accurate rendering of a patient. This rendering can be used for multiple applications including but not limited to digitizing the shape of a physician drawn treatment area and design of the electron aperture to treat this area. The decimal3D includes functionality for the electron aperture to be ordered.

User Profile

The decimal3D should be used the guidance of a physician by authorized users such as physicists, certified medical dosimetrists, radiations therapists, radiologic technologists, nurses and those who have been trained by the .decimal staff or by the clinical staff.


Product Features

decimal3D will handle patient data entry. The user will be able to take a three dimensional scan of the area where the physician has outlined the area to be treated. This scan will be in full color and dimensionally accurate. From this the user can digitize the treatment area, design the electron aperture as well as place the beam. The decimal3D App also allows the user to order the aperture through and interface with the decimal Direct API.

System Availability and Data Integrity

 **Fix Me!** - We need to discuss this

Coordinates and Units of Measure

 **Fix Me!** - should we delete this for the first go round?

Data Validation

Users are responsible for confirming machine data input into decimal's p.d APP. This data will be the machine data that is used in decimal3D. 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.

Data Displays and Interpretation

decimal3D contains many displays throughout the scanning, digitizing and beam placement process.

Please refer to  **Fix Me!**.

Unauthorized Use

The decimal3D 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. 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



- this can be deleted?

Known Limitations

For a list of known system issues and limitations please refer to the following.

Release Notes

For the release notes for each version of the Planning Application, please refer to the



we need to come up with where this is.

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