



RELEASE NOTES

Voxel Dosimetry 3.2.0

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1 INTRODUCTION

These Release Notes inform users of news and improvements in Voxel Dosimetry, as well as any known issues to be aware of. Every user must be familiar with these known issues. Contact the manufacturer for any questions about the content.

This is an electronic document, a copy of which can be downloaded from www.hermesmedical.com/ifu. Hard copies of Instructions for Use, System Environment Requirements, and Release Notes are available for free (as many as number of purchased licenses) upon request.

The Release Notes and the medical device software itself is copyrighted and all rights are reserved by Hermes Medical Solutions. Neither the software nor the manual may be copied or in any other way reproduced without prior consent in writing from Hermes Medical Solutions who reserve the right to make changes and improvements to the software and the manual at any time.

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1.1 Associated documentation

- Instructions for Use:
 - o USA: P55-219 US Instructions For Use Voxel Dosimetry 3.2.0 Rev.1
 - o All other markets: P55-191 Instructions For Use Voxel Dosimetry 3.2.0 Rev.1
- PC-007 System Environment Requirements, applicable revision can be found at www.hermesmedical.com/ifu.

The Instructions For Use contains the necessary basic information to configure the application at your own preferences.

A user guidance, intended to assist users in using the software, is available in the software itself.

Warning messages are now listed in both the Instructions For Use and the user guidance. The warning messages clearly describe intended users, limitations in the software and the risks of making changes to the software.

1.2 Complaints and serious incidents

Report incidents and errors to our support, see Contact Information.

Any serious incident that has occurred in relation to the device must be reported to the manufacturer.

Depending on applicable regulations, incidents may also need to be reported to national authorities. For the European Union, serious incidents must be reported to the competent authority of the European Union Member State in which the user and/or patient is established.

Hermes Medical Solutions welcomes feedback from readers of this manual, please report any errors in content or typography and suggestions for improvements to our support, see *Contact Information*.

^{*}Subject to registration in some markets

2 NEWS AND IMPROVEMENTS

2.1 New features implemented in Voxel Dosimetry 3.0

These are the new features introduced in version 3.0 of Voxel Dosimetry since version 1.1:

- All GPU operations are performed with Compute Unified Device Architecture (CUDA) code
- Non-rigid registration for CT-to-CT alignment
- Support for additional isotopes
- Region drawing tools
- Automatic segmentation of organs
- VOI-based time-activity curve fitting
- Dose map display
- Dose-volume histogram display
- VOI-based dose calculation and tabular display
- Save and load regions as DICOM SEG files
- Automated workflow configuration options

2.2 New features implemented in Voxel Dosimetry 3.1

These are the new features in 3.1 introduced since 3.0:

- Licensing support for syngo.via/OpenApps integration added
- Add a command line option to configure the application launch so that it uses a specified spool path for passing Dose map and SEG files to an external viewer
- The results table and dose-volume histograms can be saved in csv format from the Dose tab
- Segmentation map interpolation algorithm updated

2.3 New features implemented in Voxel Dosimetry 3.2

These are the new features in 3.2 introduced since 3.1:

- Swedish GUI translation
- Update in documentation

2.4 Problems fixed and minor enhancements in version 3.0.0

These are the problems fixed and minor enhancements introduced since version 1.1:

- User interface will clearly show when the license is non-clinical
- Added list of supported isotopes to the IFU
- Added an option to change the path to the "spool" folder
- Added support for Spectrum Dynamics Veriton cameras
- A warning added to the top panel of the application window if the patient demographics of loaded studies do not match
- Date and time information added to reference studies in the dropdown menu
- Fixed issues that caused license to stop working on Windows 11
- Product information fields fixed to include all the necessary information for registered products
- Minimum number of simulated photons increased to 1 million
- Error message added if dose simulation parameters file is corrupted

- Size of the dropdown menu for selecting reference studies has been increased to include all the text for the selected studies
- Program will display a warning message if isotope is not automatically detected in the study header
- Hänscheid single timepoint approximation option is available only for Lu-177 and I-131 studies
- Effective half-life field is updated according to changes made in the therapy isotope dropdown menu

2.5 Problems fixed and minor enhancements in version 3.1.0

These are the problems fixed and minor enhancements introduced since version 3.0.0:

- Default_param files can now be saved in any location
- Added a warning message when significant changes are made by the user to dose calculation parameters
- For multiple time point calculations, automatic dose calculations are permitted only when the application is loaded with a quantitative NM data
- For single time point calculations, automatic dose calculations can only be performed using the physical half-life option or the Hänscheid approximation for Lu-177 and I-131 therapy isotopes
- Resolved a bug in segmentation map interpolation
- Resolved a bug where user-modified curves were not available in the dropdown menu after changes were made
- New command line option available to set a temporary spool path

2.6 Problems fixed and minor enhancements in version 3.2.0

These are the problems fixed and minor enhancements introduced since version 3.1.0:

- Fit override is shown in the DVH-names in Result page
- Reminder of body region is not needed if any Regions of Interest are not present
- Latin1 characters are not correctly shown or saved
- If automatic organ level TAC fit fails and reverts to physical half-life approximation, the TAC height for the physical half-life approximation is not correctly set.
- Coronal and sagittal image are difficult to handle because they are small
- The word 'Warning' should be replaced with 'Information' in the User Handbook in 3 places
- Special characters in patient name are not correctly represented in saved dosemap
- Crash on region save if special characters (umlauts) included in region name
- SEG file regions saved from Voxel Dosimetry and reloaded are not always present
- Organ level dose calculation is not correct if imaging and therapy isotope differ
- If a CT and SPECT/PET study without matching FoRs are loaded and segmentations are made, these segmentations cannot be reloaded into VD.
- Series Date/Time are set to current date/time when missing
- TAC plotting and integration can use slightly different TACs
- DICOM DT tags with with odd lengths are padded with null character when saving
- Sliders for setting W/L and UT/LT are intermittently difficult to move
- 'Seed is not ok' crash with phantom scan
- The Woodcock tracking step size selection is not identical for CPU and GPU codes
- Recovery Coefficient can be changed when it should not be
- The slice coordinate in triangulation was not taken from the middle of the slice
- Rigid registration using CT studies is not always working as well as Rigid registration in Hybrid Viewer

- Manual translation followed by Rigid moves study twice as far as it should
- Automatic curve fitting is not ideal when imaging time points are far from each other
- D% values for small volumes are not correct

3 KNOWN ISSUES

There are no known issues related to patient safety in this version of Voxel Dosimetry.

Other known issues:

- Studies which have been coregistered prior to being loaded are not recognized as such
- Dose map label not saved if series description is long
- DVH values are not visible when clicking DVH near X axis
- After using Fuzzy C-means then changing to Threshold, Fuzzy clusters parameter is set as threshold value

4 CONTACT INFORMATION

Contact any of the addresses below for service, support or if you have any other questions.

4.1 Manufacturer contact information



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4.2 Regulatory Representatives

UK Responsible Person

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