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Simplicit^{90}Y™ Quick User Guide

Personalised Dosimetry Simplified

Simplicit^{90}Y™ is a customised, easy-to-use dosimetry software developed for accelerating dosimetry planning and improving ^{90}Y SIRT workflow.

This Simplicit^{90}Y™ Quick User Guide should be read in conjunction with the main user guide, the Simplicit^{90}Y™ Help Guide, which contains important warnings, labelling and regulatory information.

Images courtesy of Centre Eugène Marquis Rennes, France.
Simplicit^{90}Y™ was developed by Mirada Medical in collaboration with BTG.

Simplicit^{90}Y™
Quick User Guide

Overview of Work Steps:

LOAD DATA

RUN WORKFLOW

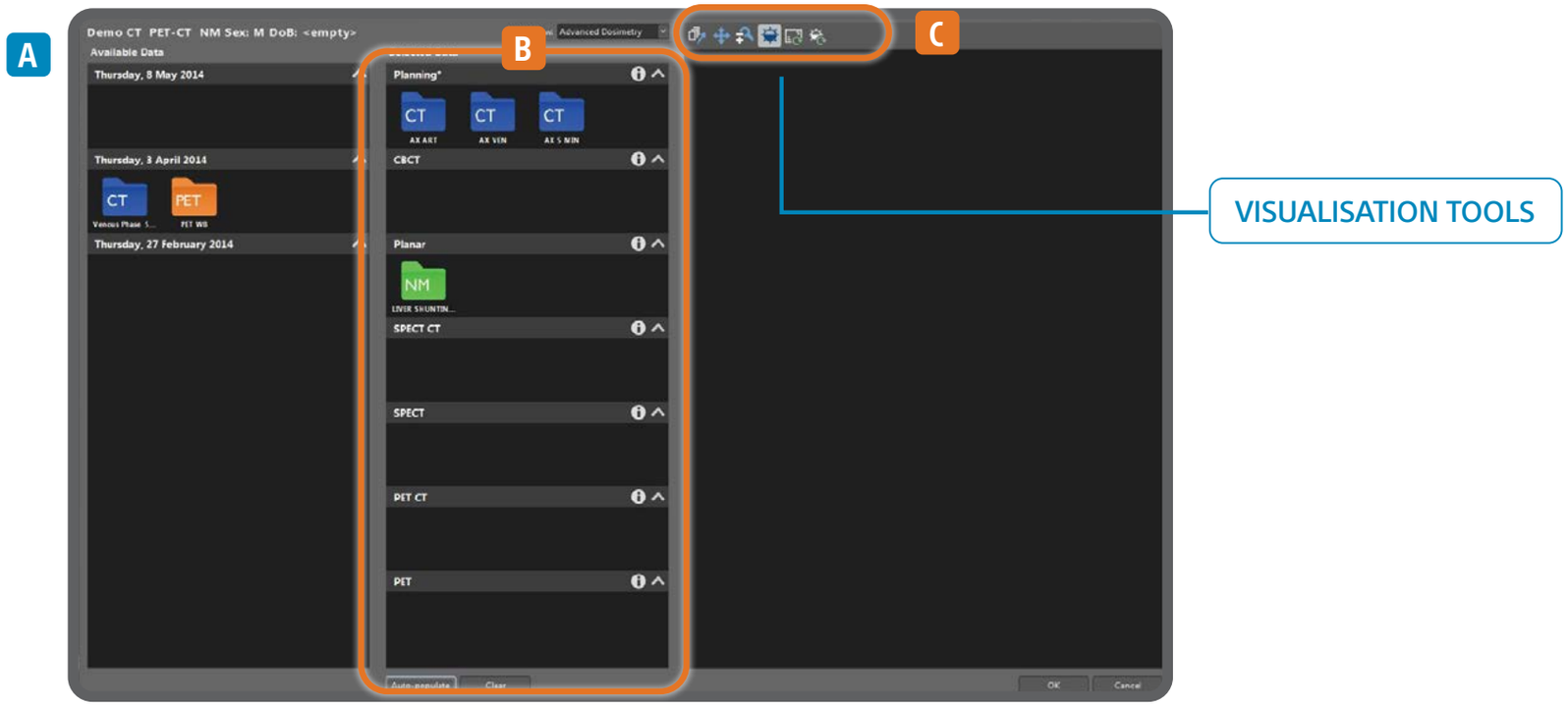
1. Overview
2. Lung Shunt Fraction
3. Registration QC
4. Segmentation
5. Standard/Multi-compartment Dosimetry
6. Report

SAVE

CHANGE SYSTEM CONFIGURATION

Load Data

- **Access** Simplicit^{90}Y™ through Mirada DBx database
- **Load** available data in the database by selecting data series at patient, study, or series level; **Select Data** dialogue will appear **(A)**
- **Assign** loaded series to relevant role (i.e. function in the dosimetry analysis) by right-clicking or by dragging folder from Available Data panel to chosen role **(B)**
  - Mandatory roles include “Planning”
- **Preview** data series by clicking on folder icon for desired series
  - Visualisation tools become available **(C)**
- **Click OK** to run workflow with the selected data series
  - If ‘OK’ button is not enabled or if a warning message is displayed, please refer to the full Simplicit^{90}Y™ User Manual for **troubleshooting**

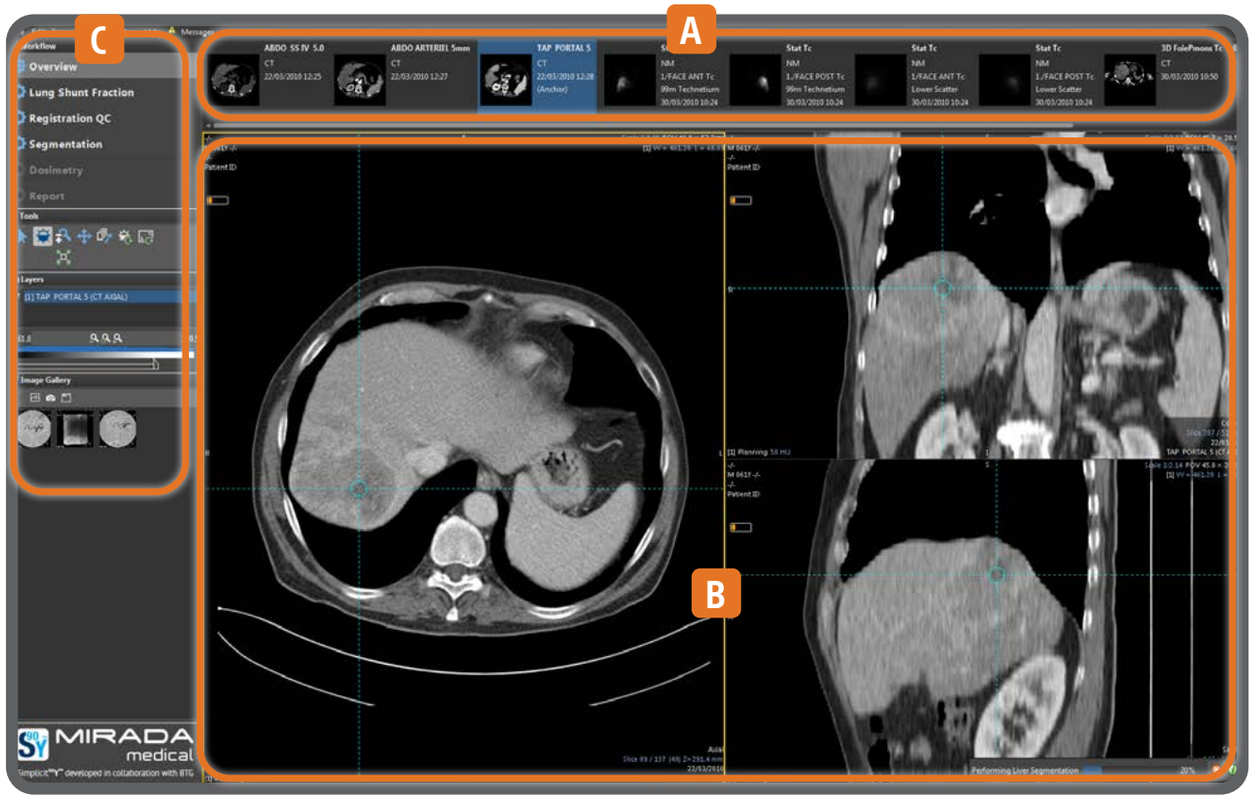


PET = positron emission tomography;
SPECT = single-photon emission computed tomography

Run Workflow

1. OVERVIEW

- Workflow opens in “Overview” screen which allows visualisation of loaded series
- User interface consists of 3 areas (A, B, C)



A. DATA BROWSER

- Select data to be displayed in the Viewing Area, or select phase used as anchor for registration (when multiphase series loaded)

B. VIEWING AREA

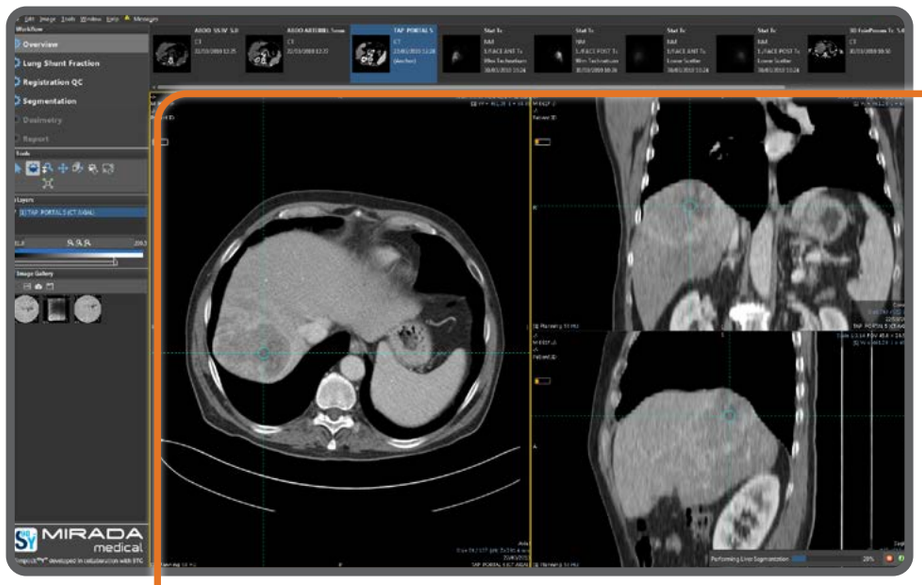
- Information about patient, study, and images
- Displays available control options
  - Scale
  - Window and Level
  - Quantification Options
  - Slice Index

Run Workflow

1. OVERVIEW cont.

B. VIEWING AREA

- Active text appears as blue, used to adjust image
- Inactive text appears as black/white



Patient Name Sex | Age | Birth Date Institution Name Accession Number		Scale Label Window/Level Controls
Dataset Name | Quantification		View Type Slice X / Y Series Date Series Description

Current zoom factor applied and modification controls

From DICOM data

Name of data role to which data has been assigned

Value at crosshair location

Run Workflow

1. OVERVIEW cont.

Workflow

- Steps required for dosimetry calculations

Image Visualisation Tools

- Image manipulation tools which affect the active viewport: (e.g. zoom, pan, undo)

Layer Manipulation Tools

- Tools used to selectively manipulate image layers

Segmentation Tools

- Tools used to create, edit, and apply post-processing operations to structures

Structures

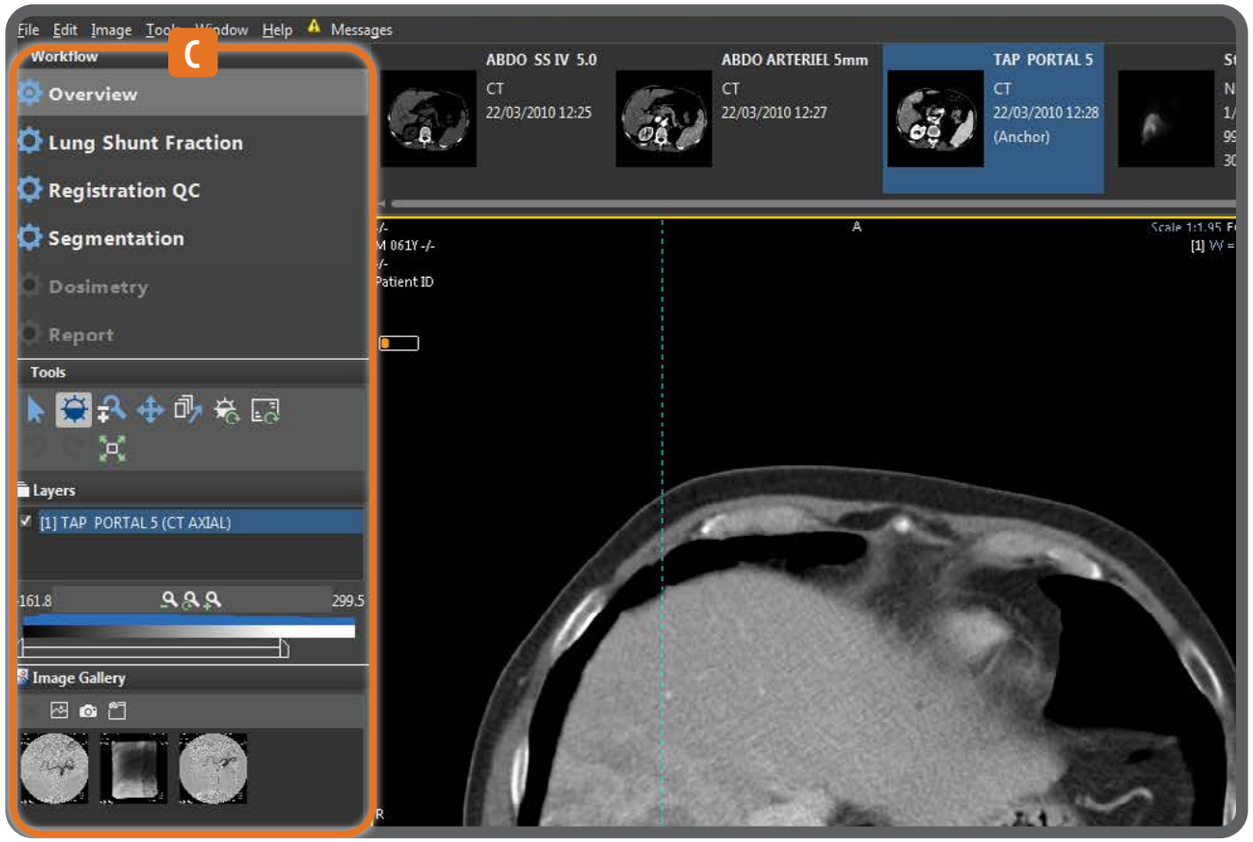
- Allows editing of structure attribute details of the ROIs/VOIs created during segmentation

Image Gallery

- Houses bookmarks, key images, snapshots, or secondary captures created during the session which may be included in report

C. TOOLBOX

- Tools available during workflow steps
- Consists of 6 areas/panels
- Options in Panels 2 to 6 depend on step selected in **Workflow** panel



ROI = region of interest; VOI = volume of interest

Run Workflow

2. LUNG SHUNT FRACTION (LSF)

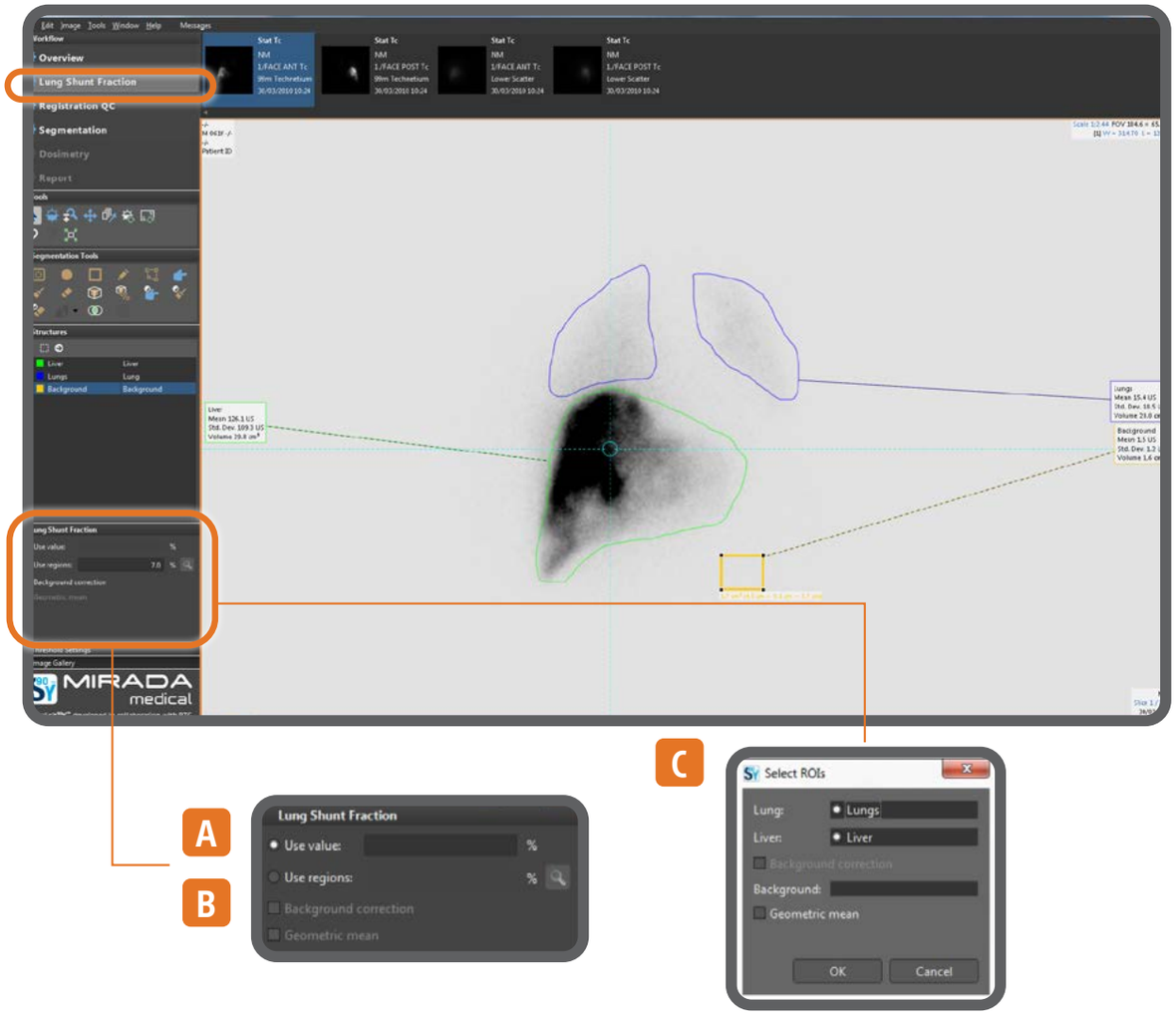
Allows definition and calculation of nontarget lung radiation dose

User-defined value

- Select "Use value" **(A)** and type value in text field

Automatically estimated value

- Draw lung and liver ROIs with any tool in Segmentation Tools panel
- Assign lung and liver ROIs to relevant type (from Structures dialogue)
  - Available types: Lung, liver, background
- Select "Use regions" **(B)**
  - Select ROIs dialogue opens **(C)**
  - Lung and liver fields will be populated with all ROIs assigned to lung and liver roles
  - LSF will be populated with value calculated by software



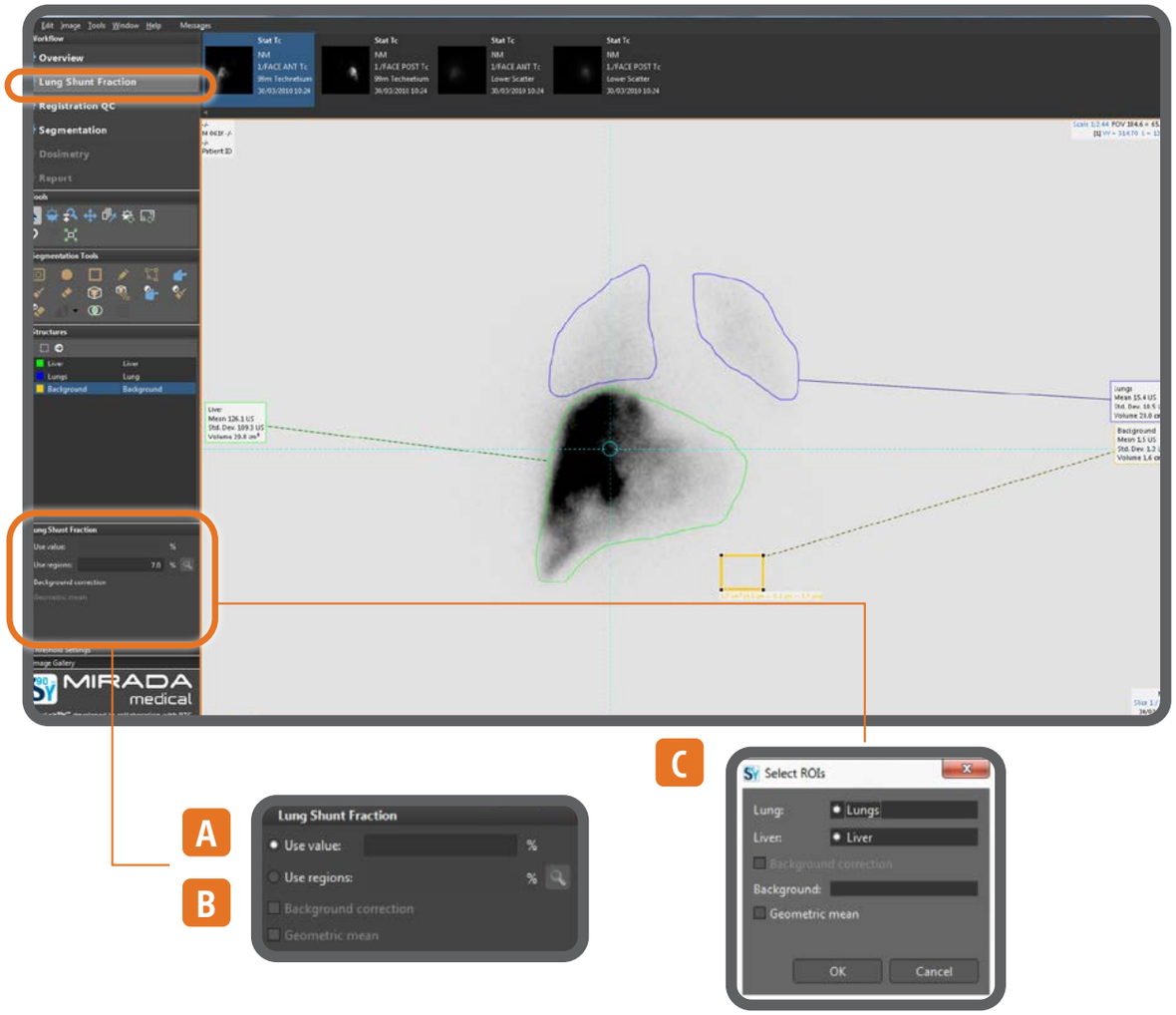
LSF = lung shunt fraction; ROI = region of interest

Run Workflow

2. LUNG SHUNT FRACTION (LSF) cont.

Allows definition and calculation of non-target lung radiation dose

- Option: Background correction for liver and lung regions
  - Create a region, assign it to "Background" type, left-click LSF select icon, and tick Background correction
- Option: Geometric mean of counts from each image used in LSF calculation
  - Possible in cases where dual head data has been loaded



LSF = lung shunt fraction

Run Workflow

3. REGISTRATION QC

Allows assessment and editing of registration applied to loaded datasets

A Registrations Area

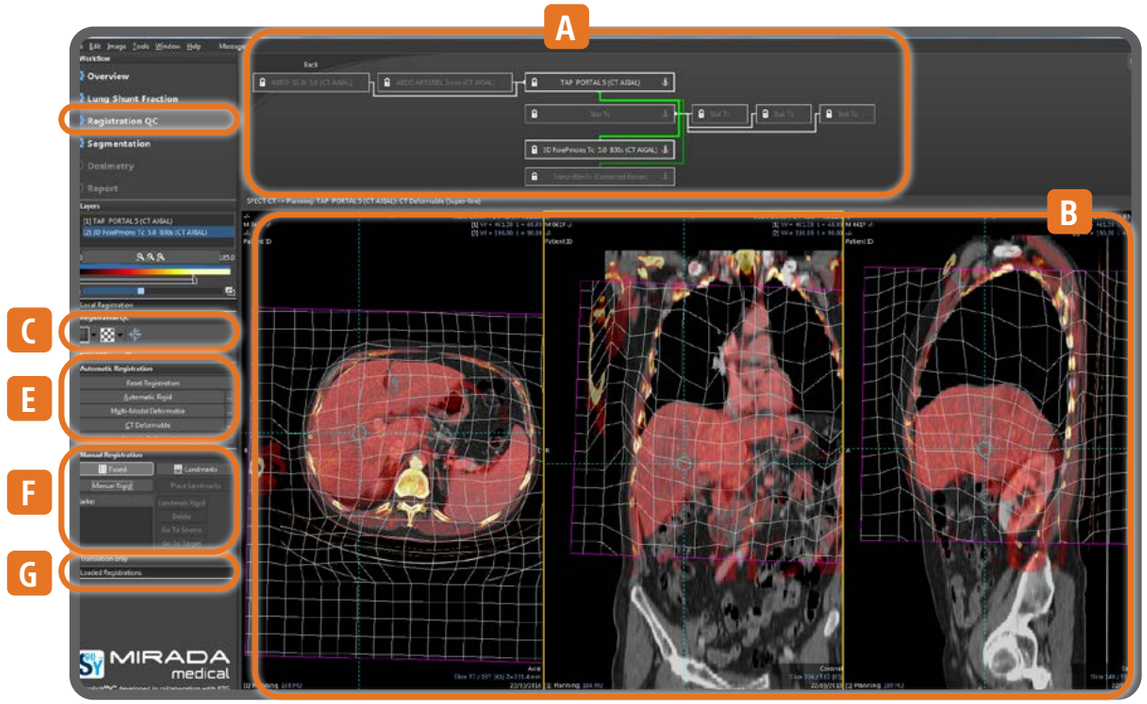
- Graphical representation of relationships between loaded datasets
  - Box = series
  - Black line = datasets that share same frame of reference and are hardware locked (displayed with lock icon)
  - Red line = rigid registrations
  - Green line = deformable registration
- Click on lines between boxes in Registration Area to select relationship; datasets will be displayed in Image Area

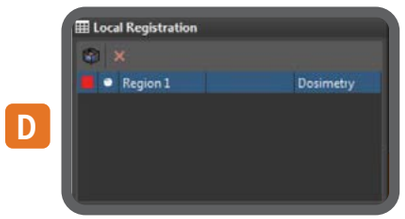
B Image Area

- Includes tools to review, evaluate, or manipulate registration

C Registration QC Panel

- Drop-down menu reveals tools available to visualise displacement following image registration





Run Workflow

3. REGISTRATION QC cont.

Allows assessment and editing of registration applied to loaded datasets

D Local Registration Panel

- Allows restriction of algorithm operation within a specific region of the image, which may result in improved results
- Structures that can be used for local registration are listed

E Automatic Registration Panel

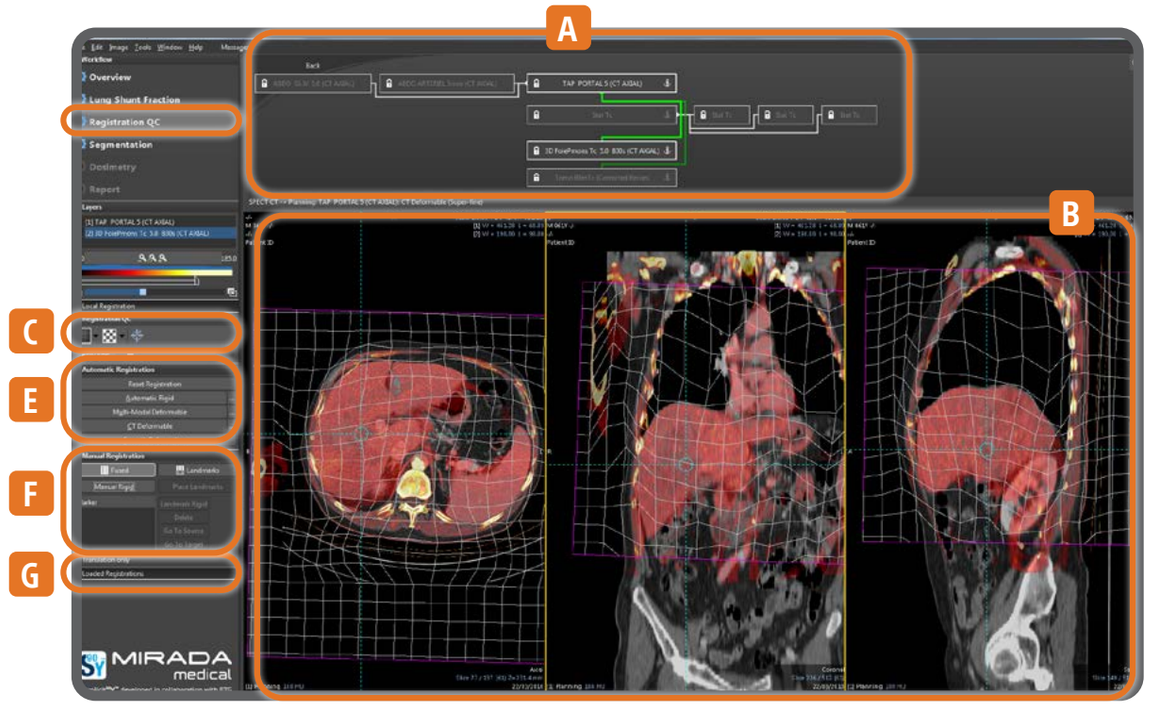
- Tools include: Reset Registration, Automatic Rigid, Multi-Modal Deformable, CT Deformable, Smooth Deformable

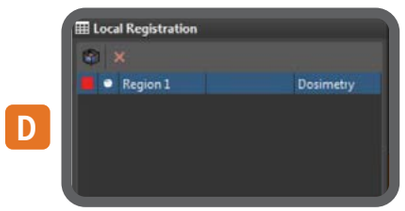
F Manual Registration Panel

- Provides means to define transformation between 2 datasets
- Relies on visual examination of registration

G Loaded Registrations

- Allows a loaded registration to be applied when relationship for which it was created is displayed





CT = computed tomography

Run Workflow

4. SEGMENTATION

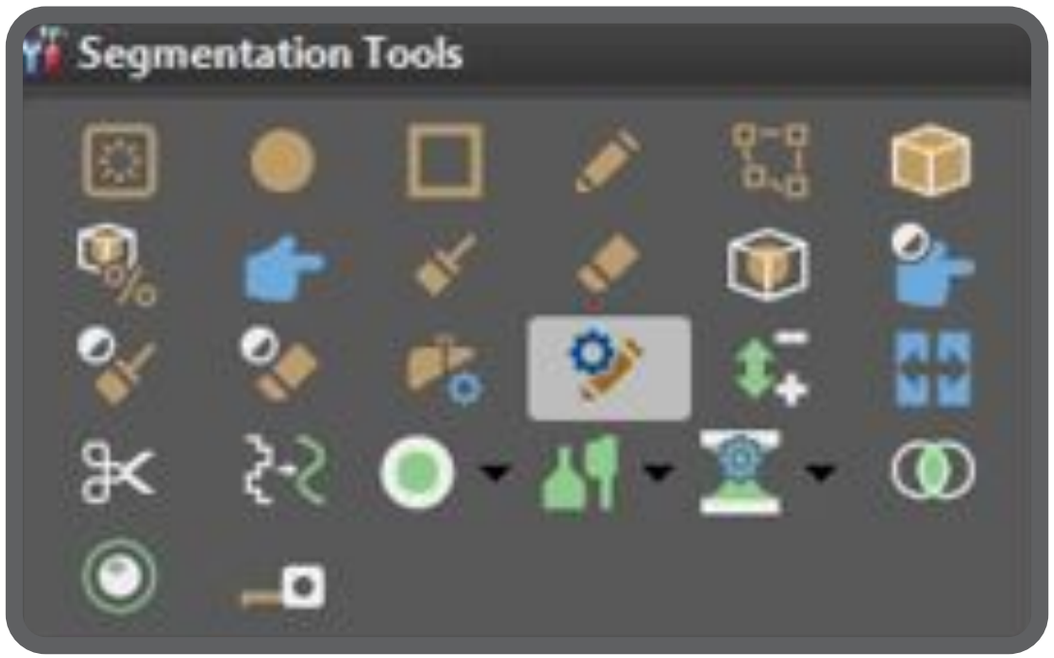
Allows definition of regions (2D) and volumes (3D) of interest (ROI, VOI) with tools available in Segmentation Tools panel

- Select dataset from Data Browser **(A)**; selected series is displayed in image view
- Create VOI using Segmentation Tools
  - Structures attributes **(B)** dialogue box appears, allowing naming and description of VOI
- "Type" drop-down allows assignment of VOI to a dosimetry type, i.e. group of VOIs that are available to contribute to dosimetry for that group:
  - Whole liver **(C)**
  - Perfused volume
  - Tumour **(D)**
  - Viable tumour
  - Normal tissue
  - None (used for anatomical structures not listed, e.g. portal vein thrombosis)
- ROIs/VOIs created will be listed in Structures panel

2D = two-dimensional; 3D = three-dimensional;
ROI = region of interest; VOI = volume of interest

Run Workflow

4. SEGMENTATION cont.



MULTIPLE SEGMENTATION TOOLS ARE AVAILABLE:

Manual (Freehand)

- Click and drag to create a 2D region

Adaptive

- Click and drag to create a 2D region on a CT or MR image; the system will automatically segment the pixels within the defined region

Automatic

- Click to run automatic liver segmentation on the selected CT series

2D = two-dimensional; CT = computed tomography; MR = magnetic resonance

Run Workflow

4. SEGMENTATION cont.

MULTIPLE SEGMENTATION TOOLS ARE AVAILABLE:

Interpolate slices

- Click to allow system to calculate and fill in contours based on those drawn on other slices
- Drop-down options includes linear, cubic, quadratic, or adaptive interpolation

Boolean

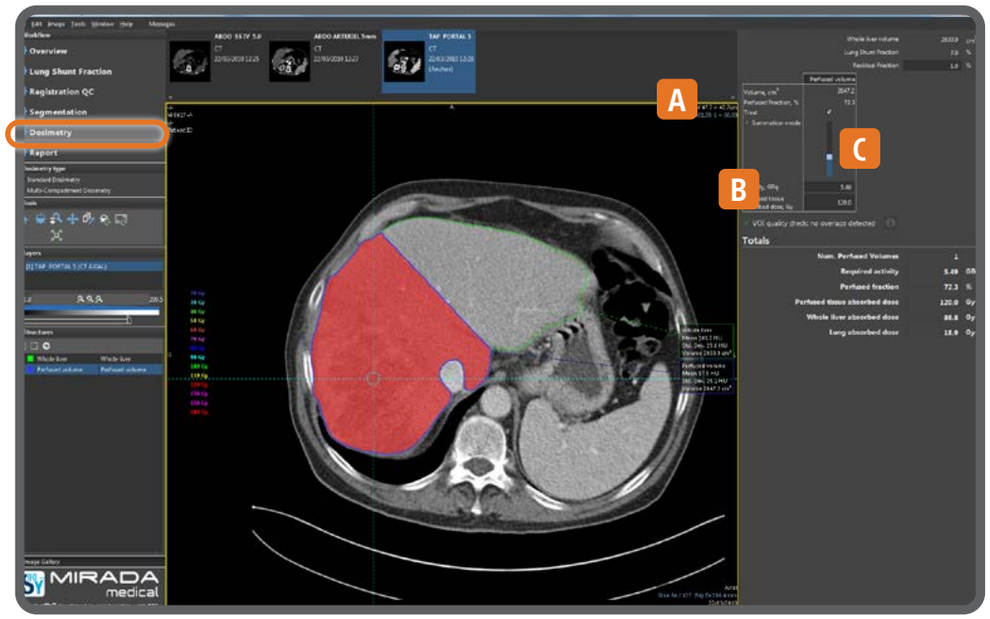
- Click to perform Boolean operations between two structures
- Supported operations include:
  - Union (a structure covering the same area as the selected structures)
  - Minus (removes from the first structure any areas overlapped by the second)
  - Intersection (a structure containing only the area where the two structures overlap)

Run Workflow

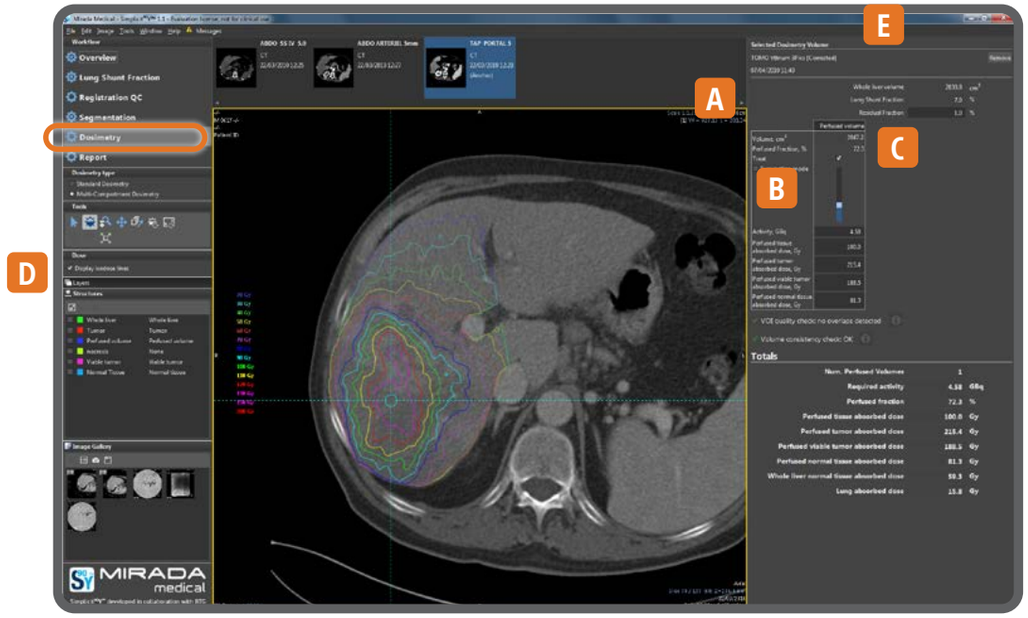
5. DOSIMETRY

Allows calculation and visualisation of absorbed dose to tissue

- Accessible after:
  - LSF value has been defined
  - At least one VOI has been assigned to the Perfused Volume dosimetry type
  - A Whole Liver VOI has been defined
  - A SPECT or PET dataset has been loaded (*for Multi-Compartment Dosimetry*)



- Click **Treat** check-box **(A)** to enable **Target activity slider** as well as **Target activity** and **Perfused tissue absorbed dose** fields
  - If more than one VOI has been assigned to the Perfused volume type, selecting the **Summation box (B)** will allow more than one **Treat** checkbox to be selected

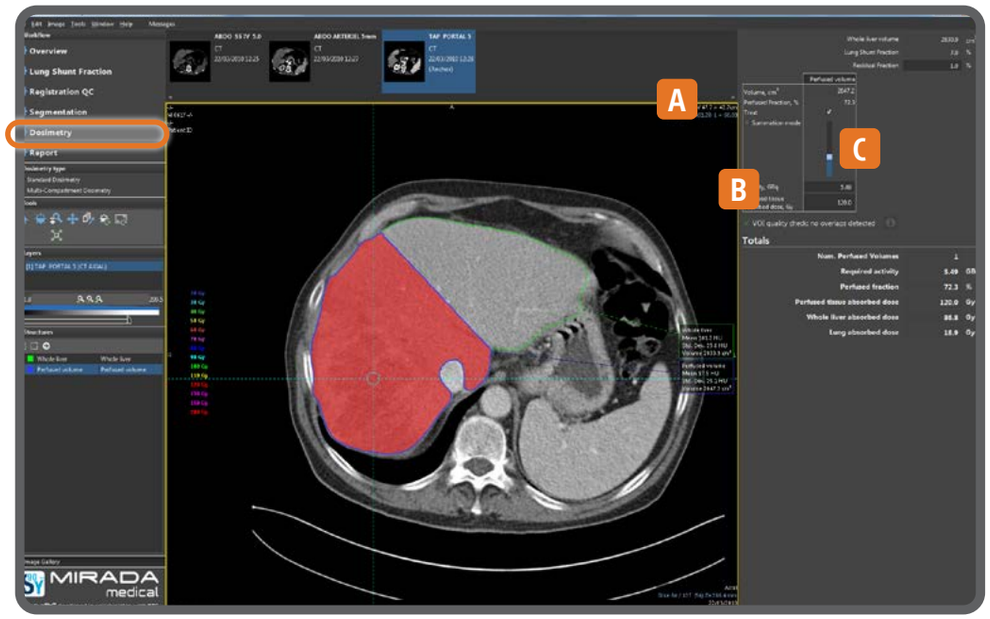


LSF = lung shunt fraction; PET = positron emission tomography;
SPECT = single-photon emission computed tomography; VOI = volume of interest

Run Workflow

5. DOSIMETRY cont.

- Enter target activity or drag slider **(C)** up/down to increase/decrease the injected target activity value
- Affected absorbed doses will be updated accordingly, and corresponding VOI will be displayed in colour overlay determined by isodose colour map and current dose
  - *For Multi-Compartment Dosimetry*, click the **Display isodose lines** checkbox to display isodose contours instead of the colour overlay **(D)**
- Post-treatment absorbed dose can be confirmed by comparing data from Tc-99m and ^{90}Y scans **(E)**



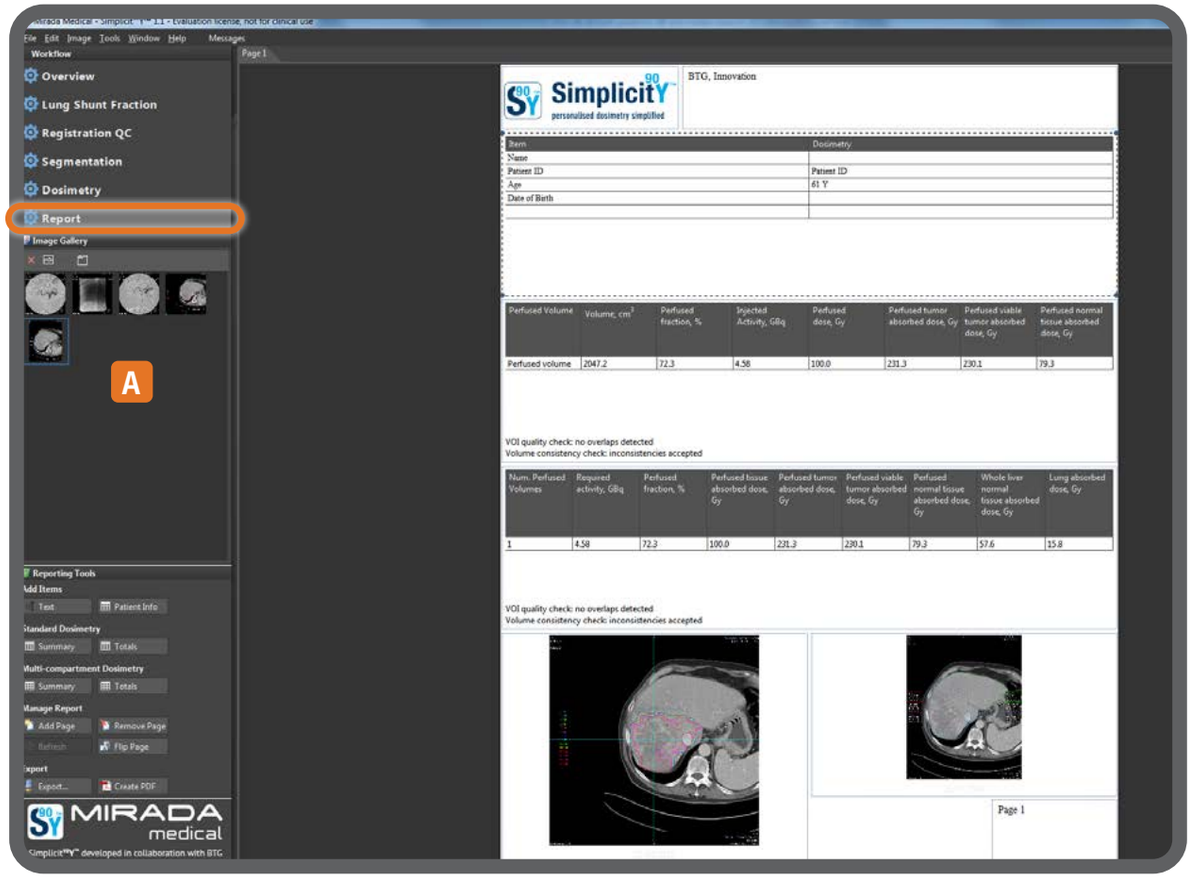
90Y = yttrium-90; Tc-99m = technetium-99m; VOI = volume of interest

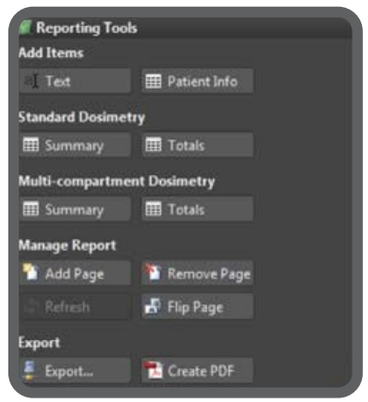
Run Workflow

6. REPORT

Allows creation of report for export to database or to save as PDF

- Image Gallery and Reporting Tools become accessible once Report screen is entered
- **Image Gallery (A)** includes saved key images or bookmarks
  - Double-click or drag-and-drop images into report
- **Reporting Tools (B)** includes controls to add information to report or to manage information in report





B

Save

- Session may be saved, including:
  - regions
  - key images
  - registration
  - and dosimetry results

- Reloading session includes:
  - restoration of registrations,
  - structures,
  - key images,
  - modified quantification parameters and its associated images, anchor phase, and dosimetry values

Change System Configuration

- Various program settings may be configured from **Tools > Options...**
- Select desired tab
  - Default Series
  - Dose
  - Institution Details
  - Quantification
  - Report
  - Save and Export
  - Segmentation
- Make changes in tabs
- Click **Apply**
- Click **OK**

Simplicit^{90}Y™

Personalised Dosimetry Simplified

Manufacturer and Device Information

In compliance with Council Directive 93/42/EEC
Manufactured by:
Mirada Medical Ltd
New Barclay House
234 Botley Road
Oxford OX2 0HP
United Kingdom

Technical Support

For technical or application support, please contact Mirada Medical using the applicable support phone number or by sending an email to the support email address:
USA: 877.872.2617
Outside the USA: 0845 459 0141
support@mirada-medical.com

Intended Use

Simplicit^{90}Y™ is a standalone software device intended for use by Nuclear Medicine (NM) or Radiology practitioners. The intended use of the system is to provide digital processing, review and reporting of medical images, including data display, quality control, image manipulation and quantification analysis capabilities. Software components provide functions for performing operations related to image display; manipulation, analysis and quantification and can operate on computer workstations.

Indications for Use

Simplicit^{90}Y™ can run on a dedicated workstation and is intended for use by Nuclear Medicine (NM) or Radiology practitioners for display, processing and reporting of NMI data, including planar scans (Static, Whole Body) and tomographic scans acquired by gamma cameras or PET scanners.

The NM or PET data can be coupled with registered with anatomical scans from other modalities including fused CT or MR scans, and with physiological signals in order to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes.

The system is intended to be used by physicians for viewing and assessing image data for general clinical diagnostic purposes with additional features and optimized workflow for ^{90}Y dosimetry.

Please refer to the user manual for full warning, labelling and regulatory information.

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