

Kinepict Medical Imaging Tool

Instructions for Use



Angiography redefined



Manufacturer's Note:

This product complies with Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. The CE marking applies exclusively to medical devices introduced under this comprehensive EU regulation. The original language of this document is English

Table of Contents

0	Dokumentum információk.....	6
1	Introduction and Intended Purpose.....	7
1.1	Purpose of the Document.....	7
1.2	Intended Users.....	7
1.3	Intended Use	8
1.4	Clinical Benefit.....	8
1.5	Intended Use Environment.....	8
1.6	Performance Characteristics and Validated Claims	9
2	Safety Information	10
2.1	General Safety Information.....	10
2.2	Contraindications	10
2.3	Warnings.....	10
2.4	Precautions	11
2.5	Limitations.....	11
2.6	Residual Risks	11
2.7	Limitations of Diagnostic Use	12
3	Symbols and Abbreviations	13
3.1	Symbols.....	13
3.2	Abbreviations.....	14
4	System Requirements and Installation	16
4.1	Hardware and Software Requirements.....	16
4.2	Installation.....	17
4.3	License Management	18
5	Quick Start	19
5.1	Login	19
5.2	Loading an Image Series	19
5.3	Image Generation	20
5.4	Result Visualization	20

5.5	Export.....	20
6	User Interface	21
6.1	Main Menu	21
6.2	Toolbar	21
6.3	Workspace	21
6.4	Context Menu	22
6.5	Patient Browser.....	22
6.6	Comparison View.....	22
6.7	OR View.....	23
7	Main Workflows	24
7.1	Loading an Image Series	24
7.1.1	Loading from the File Menu.....	24
7.1.2	Loading from the User Interface.....	24
7.2	Patient Browser.....	24
7.2.1	Search by Date	26
7.3	Frame Selection.....	27
7.4	Image Generation	28
7.5	Result Visualization	29
7.5.1	Basic Visualization.....	29
7.5.2	Comparison View	29
7.5.3	Rollback View.....	30
7.5.4	OR View	31
7.6	Post-Processing.....	34
7.6.1	Basic Adjustments.....	34
7.6.2	Special Modes.....	35
7.6.3	Image Manipulation Tools.....	36
7.7	Export and Saving.....	37
7.7.1	Saving Studies	37
7.7.2	Advanced File Operations	37

7.7.3	Export Options	38
7.7.4	Quick Export.....	38
7.8	PACS Communication.....	39
7.8.1	PACS Server Management.....	39
7.8.2	Sending Images to a PACS Server	39
7.8.3	Downloading Images from a PACS Server	40
7.8.4	Automatic DICOM Receiving	40
7.8.5	Automatic Upload.....	41
7.8.6	Important Notes	41
8	System Settings and Configuration.....	42
8.1	Network and Storage Settings	42
8.1.1	Network.....	42
8.1.2	Remote Computers	42
8.1.3	PACS Servers	43
8.1.4	Automatic Upload.....	43
8.1.5	Automatic Restart.....	43
8.1.6	Storage Cleanup	44
8.2	Personal Settings.....	44
8.2.1	Creating and Modifying Profiles	44
8.2.2	Managing Profiles	44
8.2.3	Important Notes	45
8.2.4	Input Settings.....	45
8.2.5	Output Settings.....	45
8.2.6	OR View	48
8.2.7	Show/Hide Buttons.....	48
8.2.8	ICM/CO2	49
8.3	Warning Management	50
9	Maintenance and Uninstallation.....	51
9.1	Maintenance	51

9.2	Software Uninstallation.....	51
10	troubleshooting and Support.....	52
10.1	Feedback or Problem Reporting.....	52
10.2	Incident Reporting	53
10.3	Frequently Asked Questions (FAQ).....	54
11	Appendix	57
12	Related Publications	58

0 Dokumentum információk

Version Number	7.1
Manufacturer Name	Kinepict Health Ltd.
Manufacturer Address	2092 Budakeszi Kelta köz 5
Manufacturer Email	kinepict@kinepict.com
Manufacturer Website	www.kinepict.com
Basic UDI-DI Identifier	5999860492KMITSK
UDI-DI Identifier	5999860492009
Classification	The Kinepict Medical Imaging Tool is a Class IIa medical device according to Regulation (EU) 2017/745
UMDNS Code	16560

1 Introduction and Intended Purpose

1.1 Purpose of the Document

This manual contains information required for the use of the Kinepict Medical Imaging Tool, supporting the processing and evaluation of X-ray angiographic images. The purpose of this document is to assist users in understanding and correctly applying the software's functions. The software is intended for use by healthcare professionals experienced in diagnostic imaging.

This manual applies to the current version of the software.

A digital version of this manual is available at <https://www.kinepict.com>.

1.2 Intended Users

The software is intended for qualified healthcare professionals experienced in diagnostic imaging, including radiologists, interventional radiologists, and other users involved in the evaluation of angiographic examinations.

Users should possess:

- knowledge of the principles of angiographic imaging
- experience in handling DICOM-formatted images
- the professional background necessary to interpret the clinical context

Before using the software, users must familiarize themselves with the contents of this Instructions for Use and, where necessary, receive appropriate training to ensure safe and proper operation.

Use of the software remains the professional responsibility of the user and does not replace clinical decision-making.

1.3 Intended Use

The Kinepict Medical Imaging Tool is a medical device software intended for processing and visualization of DICOM-format X-ray angiographic image series. The software generates Digital Variance Angiography (DVA) images and other related image types from input image series, supporting visual image evaluation.

The software is intended to assist healthcare professionals in the analysis and interpretation of angiographic examinations. It is intended for use only by healthcare professionals experienced in diagnostic imaging. The software may be used in clinical environments, particularly during angiographic examinations and interventions, and is compatible with digital radiography and angiography systems.

1.4 Clinical Benefit

The software supports visual evaluation of angiographic images through the display of DVA images and other processed image types. The processed images may provide additional information regarding vascular status and blood flow, thereby supporting healthcare professionals in their work.

The use of the software may contribute to optimization of the imaging workflow. Information provided by the software supports clinical decision-making; however, final diagnostic and therapeutic decisions remain the responsibility of the healthcare professional.

1.5 Intended Use Environment

The software may be used in clinical environments related to angiographic imaging, including:

- Interventional Radiology
- Diagnostic Radiology
- Neuroradiology
- Image-Guided Interventions

The software may be used for both real-time (intraoperative) and retrospective (offline) image

processing. It is intended for situations where angiographic image series require processing and visual evaluation.

The intended patient population consists of adult patients (≥ 18 years of age) who are suitable candidates for angiographic examination and/or therapeutic intervention.

1.6 Performance Characteristics and Validated Claims

Digital Variance Angiography (DVA) images generated by the software may, in certain cases, improve vascular visualization compared with conventional angiographic images. Based on clinical studies, the use of DVA technology may allow reduction of contrast media volume and/or radiation exposure while maintaining image quality suitable for clinical evaluation.

The image processing methods used for DVA generation may result in a different signal-to-noise ratio compared with conventional angiographic images.

Software performance and achievable clinical outcomes depend on several factors, including:

- the imaging system used
- the examination protocol
- contrast media administration
- patient-specific characteristics

Optimization of radiation dose and contrast media usage remains the responsibility of the treating physician.

The claims presented in this section are based on clinical studies, details of which are provided in the [Related Publications](#) section of this document.

2 Safety Information

2.1 General Safety Information

The software shall only be used as described in this Instructions for Use. Images generated by the software support clinical decision-making but do not replace medical diagnosis or therapeutic decisions.

The software is intended for use only by appropriately qualified healthcare professionals. Incorrect use of the software or misinterpretation of processed images may affect clinical decision-making.

Users must familiarize themselves with the contents of this document before using the software.

2.2 Contraindications

The Kinepict Medical Imaging Tool has not been validated for thoracic, coronary, or other cardiac procedures, whether diagnostic or therapeutic.

2.3 Warnings

- Test the software before first use without a patient.
- The software does not replace DSA imaging provided by the X-ray system manufacturer.
- Respiratory motion may obscure vessels and reduce vessel visibility.
- Motion artifacts during image acquisition may hinder identification of certain clinical findings.
- Catheter movement may create significant motion artifacts that impair vascular visualization.
- Contrast medium adhering to a detached intimal layer may not be visible on the cumulative image; multiple frames should be reviewed when evaluating dissections.
- Consecutive bolus injections performed within a short time interval (seconds) do not affect the image-processing algorithms of the Kinepict Medical Imaging Tool.

2.4 Precautions

- Processed images should be interpreted together with the original angiographic images whenever possible.
- Appropriate user training is recommended before using the software.
- Modifying processing parameters may affect the appearance of output images and should be considered during interpretation.
- Evaluation of multiple image frames and different viewing angles is recommended for accurate assessment.
- The quality of the input image series and imaging conditions should always be considered during use.

2.5 Limitations

- Software performance and processed image quality depend on the quality of the input DICOM image series.
- Processed images may have limited interpretability when generated from low-quality or noisy input data.
- Software performance may vary depending on the imaging system and examination protocol used.
- Under certain imaging conditions (e.g., significant motion or insufficient contrast distribution), processed images may not provide adequate visualization.
- The software may not always be capable of displaying fine anatomical details.

2.6 Residual Risks

- There remains a risk of misinterpretation of processed images, particularly when input data quality is inadequate.
- The visual characteristics of processed images may differ from conventional angiographic images, potentially affecting interpretation.
- In certain clinical situations, the images generated by the software may not provide sufficient information for accurate assessment.
- Risks associated with software use cannot be completely eliminated; interpretation of images remains the professional responsibility of the user.

2.7 Limitations of Diagnostic Use

- The software shall not be used as a stand-alone diagnostic tool.
- Images generated by the software provide supplementary information only and do not replace conventional imaging methods or clinical evaluation.
- Diagnostic and therapeutic decisions remain the responsibility of the healthcare professional, taking into account all available clinical information.

3 Symbols and Abbreviations

3.1 Symbols

Symbol	Meaning
Symbols appearing on the label	
	Date of manufacture
	Expiration date
	Unique Device Identifier (UDI)
	Manufacturer
	Caution!
	Consult the instructions for use or its electronic version
	CE 2460 – Compliance with European standards certified by Det Norske Veritas (DNV)
	Medical Device
Symbols Used in This Document	

Symbol	Meaning
Symbols appearing on the label	
	This symbol highlights critical safety information and potential errors that could cause serious harm, severe injury, or death.
	This symbol indicates important safety information and potential issues that may cause minor harm or material damage.
i	This symbol provides supplementary information or recommendations.

3.2 Abbreviations

Abbreviation	Definition
DVA1 Image	The default Digital Variance Angiography image. This is the first image displayed during data processing, and subsequent images should be used to complement it.
DVA2 Image	A DVA-based image-processing method that improves contrast-to-noise ratio and reduces motion artifacts in lower-limb angiograms
ccDVA Image	Parameter-based image-processing techniques where color coding indicates the contrast bolus arrival time at each pixel.
Anatomical Background	An X-ray image that can be overlaid on the DVA image to display surrounding anatomy such as bones.
cumDVA video	A DVA video showing the movement of the contrast bolus front. Due to its cumulative nature, the washout phase is not visible.
ccDVA video	A DVA video using color coding to indicate bolus arrival time, helping determine when the bolus reaches specific anatomical regions.

Abbreviation	Definition
OR view	OR View (Operating Room View) is the view that the software can display on a screen located in the operating room during medical procedures.
Biplane	An imaging configuration that enables the simultaneous display and processing of angiographic image series acquired from two different imaging planes (projections).



DVA2 alone is not suitable for diagnostic purposes and must always be used together with DVA1.



ccDVA alone is not suitable for diagnostic purposes and must always be used together with DVA1.



Not suitable alone for diagnostic purposes and must always be used together with DVA1.



cumDVA alone is not suitable for diagnostic purposes and must always be used together with DVA1.



The ccDVA video alone is not suitable for diagnostic purposes and must always be used together with DVA1.

4 System Requirements and Installation

4.1 Hardware and Software Requirements

To achieve optimal performance, the Kinepict Medical Imaging Tool requires the following software and hardware configuration:

- 64-bit Microsoft Windows operating system
- Intel® Core™ i9-9900K CPU @ 3.60 GHz processor or higher-performance processor
- Minimum 32 GB RAM
- Minimum 512 GB SSD
- Monitor resolution: 1920 × 1080 @ 60 Hz (Full HD) – this setting is fixed; higher resolution is not required
- Ethernet port
- Integrated Wi-Fi and Bluetooth adapter
- Minimum 2 video output ports
- The installed software itself requires approximately 2 GB of storage space
- Ensure at least 60 GB of free storage space (HDD) for temporary files generated by the software, in addition to sufficient space for processed DICOM files to ensure uninterrupted operation

Additional hardware requirement for operating room use:

- Monitor in the operating room (recommended minimum resolution for optimal user experience: 1920 × 1080)

The following network requirements are recommended when using PACS communication, automatic DICOM receiving, or network-based data transfer:

- Minimum 100 Mbit/s network connection
- 1 Gbit/s Ethernet connection recommended for optimal operation
- Firewall-protected and secure hospital network environment

The network infrastructure must be configured together with local IT specialists and the PACS system administrator.



Do not use the Kinepict Medical Imaging Tool on a computer that does not meet the minimum requirements listed above.

4.2 Installation

In most cases, the software is delivered pre-installed.

If the software is not installed, follow the steps below.

Installation Steps

- Extract the provided installation package (.zip installation package)
- Open the extracted folder
- Run the Kinepict_setup.exe file
- Select the installation destination folder
- Choose whether a desktop shortcut should be created
- Click the “Install” button
- After the installation is completed, click the “Finish” button. (If the automatic startup option is enabled, the software will start automatically and the login interface will appear.)

If the installation is not performed by Kinepict Health Ltd., it is mandatory to complete the current installation checklist document titled:

“L-SOP010-002 Installation Checklist – Software Module”

during the installation process.

4.3 License Management

During the initial installation, the software is delivered with an active license.

License renewal is the responsibility of the user.

Before license expiration, the user receives an email notification.

Prerequisites

- Valid user account
- Internet connection
- Installed software

License Activation

- Open the license renewal email
- Follow the link provided in the email
- Log in to the website using your username and password
- Enter the machine identifier and select the desired license duration
- Submit the license request
- After successful request approval, download the provided license file (.dat format)
- Start the software
- Select the “Browse” option and locate the downloaded license file
- Click the “Install” button

5 Quick Start

5.1 Login

To use the software, the user must log in after startup.

Login is performed through the local login interface, where the user can either sign in with an existing account or create a new user account.

Local user accounts are available only on the given computer. These accounts are not synchronized with other systems or online services.

Creating a User Account

- When creating a new user account, the following information must be provided:
 - username
 - password
 - password reminder
 - acceptance of the Terms of Service

Login Options

- The following options are available on the login interface:
 - Remember username: the system stores the username and automatically fills it in during the next startup
 - Automatic login: the software automatically logs in the most recently used user during startup
 - Automatic startup: the software starts automatically after Windows login

5.2 Loading an Image Series

Load the desired angiographic image series into the software for processing.

To load an image series, click the Open button, then select the desired image series in the file browser

window and open it.

After loading, the image series appears in the software input window.

Alternatively, the image series can also be selected using the Patient Browser, where folders and files can be browsed and selected.

5.3 Image Generation

Select the image frames from the loaded image series that should be used for processing.

After the selection is completed, start image generation by clicking the “Generate” button.

Once processing has started, DVA image generation runs automatically.

If necessary, the process can be interrupted by clicking the “Cancel” button.

5.4 Result Visualization

After image generation is completed, the processed images appear in the software interface.

The displayed images support clinical evaluation.

The user can apply post-processing functions and add annotations to the generated images.

5.5 Export

To export the generated images, select the export function.

In the export window, specify the save location and select the desired image type and export format.

If required, anonymization of the exported data can also be enabled.

6 User Interface

6.1 Main Menu

The main menu is located in the upper menu bar of the software and provides access to the most important system functions. The main menu consists of four primary sections: “File”, “Edit”, “Settings”, and “Help”. A language selection icon is also available on the right side of the menu bar.

The “File” menu contains functions related to opening image series, saving studies, exporting, anonymization, and closing sessions.

The “Edit” menu contains functions related to image generation, post-processing, and image modification operations.

The “Settings” menu contains system, network, PACS, personal, and warning management settings.

The “Help” menu provides access to documentation, license information, feedback submission, language selection, and additional support-related functions.

6.2 Toolbar

The toolbar provides quick access to frequently used functions. Using the toolbar, the user can directly perform common operations such as opening image series, starting image generation, exporting data, or applying post-processing functions.

The purpose of the toolbar is to ensure that frequently used workflow functions are available not only through the menus but also through dedicated shortcut buttons.

6.3 Workspace

The workspace is used to display image series, input image frames, and generated results.

The content of the workspace changes depending on the current stage of the workflow:

- after loading an image series, the input image frames are displayed
- after image generation, the generated images and videos are displayed
- during post-processing, the selected image can be modified
- in rollback view, previously generated images can be reviewed



Before first use, the user must test all required functions to verify proper operation before applying them in clinical use.

6.4 Context Menu

The context menu is accessible by right-clicking certain areas of the user interface. The context menu displays functions related to the currently selected object or workflow step.

The context menu may provide quick access to functions such as:

- file opening options
- image generation
- export
- post-processing functions
- comparison view
- annotation

6.5 Patient Browser

The Patient Browser appears in a separate window and is used for reviewing, filtering, and selecting processable image series. The user can select patient data or image series from different sources, such as default folders, remote folders, or external storage devices.

The detailed usage of the Patient Browser is described in the Main Workflows section.

6.6 Comparison View

The Comparison View is a separate window function that allows multiple generated images to be displayed and compared simultaneously. The purpose of this view is to support more accurate

evaluation by allowing different processing results to be examined side-by-side in enlarged format.

The Comparison View can be accessed from the main workspace, for example by double-clicking an image or selecting the appropriate option from the context menu.

6.7 OR View

The OR View is a display mode designed for use during interventional procedures. The OR View is typically displayed on a monitor located in the operating room and allows real-time visualization of processed images.

The interface has a simplified design that provides fast and clear access to essential functions. The available functions in the OR View represent a limited subset of the main window functions, restricted to the operations most commonly required during use.

The OR View also supports Biplane visualization mode. Configuration of this functionality should be requested from the distributor or from Kinepict.

7 Main Workflows

7.1 Loading an Image Series

Multiple options are available in the software for loading image series.

7.1.1 Loading from the File Menu

Within the “Open” section of the File menu, the user can choose from the following options:

- Open File: The selected file can be opened using the Windows file browser.
- Open Folder: The contents of the selected folder are displayed in the Patient Browser window.
- Open Patient Browser: The Patient Browser can also be opened in a separate window.

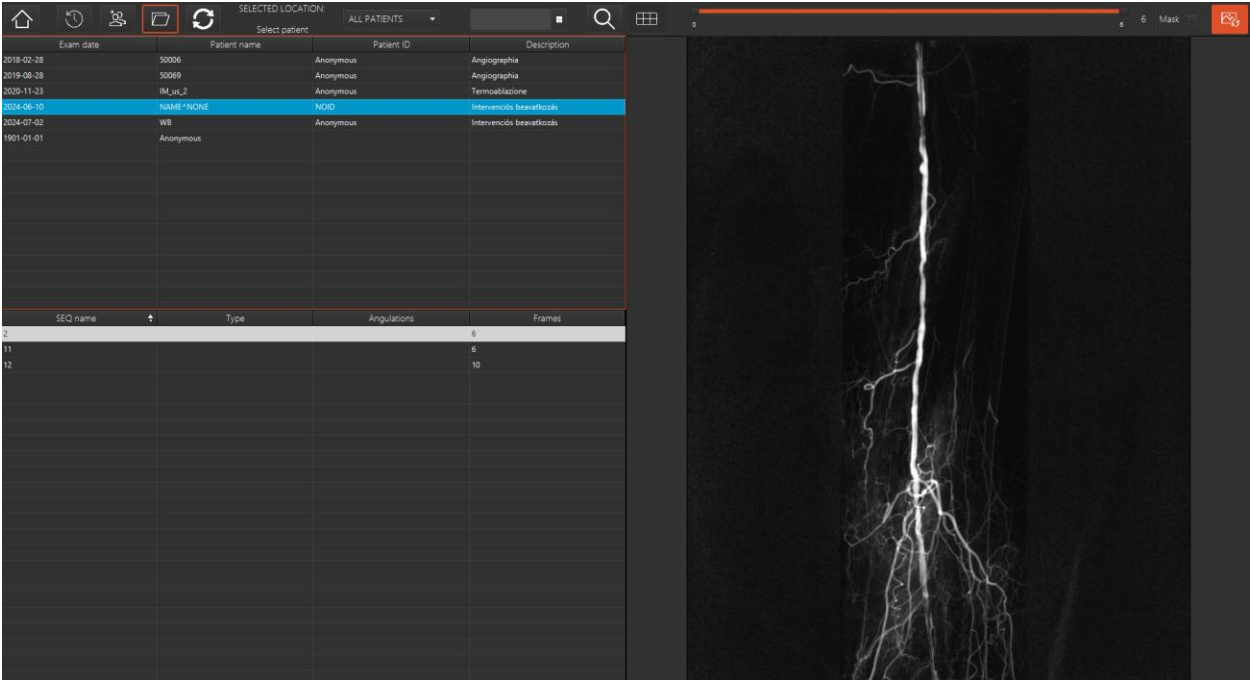
7.1.2 Loading from the User Interface

By right-clicking the corresponding button located in the left-side menu bar of the user interface, the following options become available:

- Open File:
The desired file can be selected using the Windows file browser.
- Open Patient Browser:
The image series can be selected through the Patient Browser, which provides a more structured and organized interface.

7.2 Patient Browser

The Patient Browser allows the user to review and select processable image series. The Patient Browser appears in a separate window, where available patients and their associated image series can be viewed in a detailed list format.



“Change to Main Window” button: Returns the user to the main application window.



“Last Examined Patient” button: Reloads the files associated with the most recently examined patient.



“All Patients” button: Loads the contents of the previously configured remote folder.



“Select Patient” button: Allows browsing and selecting a folder.



“Refresh Current Folder” button: Refreshes the currently loaded folder within the Patient Browser.

7.2.1 Search by Date

The Patient Browser provides the ability to filter examinations by date.

Using the date selection field (datepicker), the user can define either a specific day or a date range, and the system will display only examinations performed within the selected period.

- Selecting a single day:

Click the date selection field, then select a day from the displayed calendar. Afterward, click the “Search by Date” button. The result list will display all patients examined on the selected day.

- Selecting a date range:

Select the first day using the left mouse button, then click another day to define the end date of the desired interval. The selected range includes both selected days and all dates between them. By clicking the “Search by Date” button, the system displays all patients whose examinations were performed within the selected interval.

- Clearing the selection:

When the date selection field is open, right-clicking clears the current selection and restores the default list view.

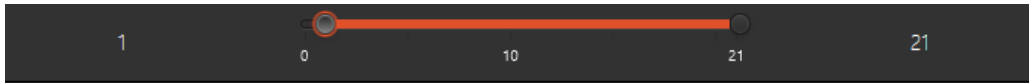
The drop-down list located below the date selection field provides quick access to predefined time periods:

- Today
- Yesterday
- Current Week
- Current Month
- Before Today
- All Patients (display all examinations without date restriction)



This button allows switching between mosaic view and preview DVA1 image view.

- Individual image frames can be selected or excluded from data analysis in mosaic view.



- The frame selection bar simplifies the selection of consecutive image frames.

7.3 Frame Selection

Before DVA image generation, the user can select the image frames that will be included in the processing.

Selected frames are highlighted with an orange border.

Selecting Frames

- To select individual frames, click the desired frame.
- To select multiple consecutive frames, use the Shift + left mouse button combination.

Managing Selections

- The “SELECT ALL” button selects all available frames.
- The “DESELECT ALL” button excludes the selected frames from processing.

Range-Based Selection

Using the range selection field, multiple frames can be selected by specifying a numerical range.

Example: 1–4, 7–10

The selection is applied by pressing the Enter key.

Viewing Frames

- Double-clicking a selected frame opens it in enlarged view.

7.4 Image Generation

Image processing can be started using the “Image Generation” function.

The software supports the following DICOM image series types:

- XA (X-ray angiography)
- DX (Digital Radiography / Digital X-ray)
- RF (Radiological Fluoroscopy)

Image generation can be started using the orange-colored “Image Generation” button located in the user interface. The process can be interrupted by clicking the “Cancel” button.

In the Patient Browser, image generation can also be started using the button located in the upper-right corner.

During processing, the system generates DVA1 images and additional DVA-based image types.

The DVA1 image type is always generated, while additional image types can be configured in the “Personal Settings” menu.

7.5 Result Visualization

7.5.1 Basic Visualization

After image generation, two images from the selected image types are displayed side-by-side on the screen according to the configured settings. If multiple image types are generated, they can be selected from the drop-down list located above the images. The generated images can be directly reviewed and used for further processing.

The upper bar of the main window displays the following information:

- patient name
- patient birth date
- patient ID
- examination date
- SEQ name
- number of images

The navigation buttons allow the user to:

- show the input view
- show the rollback view
- show the output view
- show the DICOM's details

7.5.2 Comparison View

For detailed image evaluation, the user can open the Comparison View.

The Comparison View can be opened by:

- double-clicking the desired image
- right-clicking the image and selecting "Open in Comparison View" from the context menu

The Comparison View appears in a separate window and allows multiple generated image types to be displayed simultaneously side-by-side for direct comparison. The view supports visual comparison of different processing results.

The header provides options for:

- change to main window
- selecting the comparison layout mode

The side panel contains buttons for:

- hiding and displaying the header
- removing the selected image from the view
- hiding and displaying rollback images
- exporting the screen in image format
- sending the current view to PACS
- refreshing the rollback image list

7.5.3 Rollback View

The rollback mosaic view allows the user to review previously generated images associated with the selected patient.

To use this function, rollback visualization must be enabled in the “Personal Settings” menu.

In the rollback view, images from previous generations are displayed in mosaic layout, allowing the user to review and compare earlier processing results.

If the OR View is active, live synchronization can also be enabled.

In this mode, modifications performed in the main window (e.g. image switching, post-processing) are displayed in real time on the OR screen, including navigation performed within the rollback view.

The live synchronization can be enabled or disabled using the icon displaying two circular arrows located in the upper toolbar of the main window.

7.5.4 OR View

The OR View is a specialized visualization mode of the Kinepict Medical Imaging Tool designed to support real-time image display during interventional procedures. The purpose of this mode is to provide processed images in a simplified, quickly interpretable, and clinically optimized format.

The OR View is typically displayed on a separate monitor in the operating room and supports both Single Plane and Biplane display modes. In Biplane mode, different views (e.g. frontal and lateral images) can be displayed simultaneously side-by-side.

7.5.4.1 Screen Layout

The OR View interface consists of several well-separated sections.

Main Display Area:

The central area of the screen displays the generated images or videos. The displayed content depends on the selected image type and current configuration.

In Biplane mode, two images are displayed side-by-side.

7.5.4.2 Left Toolbar

The left-side toolbar contains frequently used core functions:

- Cursor position indicator: displays the current cursor location on the image
- Image type selection buttons (e.g. DVA1, DVA2, ccDVA): instant switching between displayed image types
- ICM/CO2 switch: quick switching of contrast agent type
- Quick export buttons (PNG, JPG, TIFF): immediate export of the current image
- Warning icon: displays system messages and warnings

Clicking an image type immediately updates the displayed content.

7.5.4.3 Right Toolbar (Post-Processing)

The vertical toolbar on the right side contains post-processing tools that can be directly applied to the displayed image.

Available functions include:

- brightness/contrast adjustment
- automatic brightness/contrast
- pixel shift (multiple modes)
- color inversion
- anatomical background visualization
- sharpening
- undo / redo
- view switching (e.g. frontal/lateral view in Biplane mode)

The functions can be activated with single-click operation, supporting fast and efficient use in the operating room environment. The available functions can also be configured in the Personal Settings menu.

7.5.4.4 Rollback Panel

The rollback panel is located on the right side of the screen (or in a separate panel) and displays previews of previously generated images.

- the user can return to previous generations
- selected images can be restored
- images are displayed together with their current post-processing state

This allows rapid comparison between current and previous results.

7.5.4.5 Header

The header located at the top of the screen displays examination-related information:

- patient name
- date of birth
- patient ID
- examination date
- series number

The header and certain side panels can be hidden to maximize the display area.

7.5.4.6 Interaction and Operation

User interaction in the OR View is intentionally minimized to support fast and safe operation.

- post-processing tools can be activated with simple mouse clicks
- image modifications appear immediately
- operations performed in the main window can be mirrored in real time in the OR View

This ensures that the currently active state is always visible during the procedure.

7.5.4.7 Profile Switching

The OR View contains a dedicated page where the user can switch between available profiles using mouse selection.

7.5.4.8 SMPTE Phantom

The OR View includes an SMPTE test pattern used for display calibration verification.

7.5.4.9 Important Notes

- OR View configuration can be modified in the Settings menu
- Enabling or disabling Biplane mode is configuration-dependent
- The displayed image types and behavior depend on the output and personal settings
- System modifications may affect OR View visualization

7.6 Post-Processing

The software provides post-processing tools for fine-tuning and visual optimization of generated images.

The purpose of post-processing operations is to improve image interpretability and support clinical evaluation.

Post-processing functions are available through the following interfaces:

- the “Edit” menu
- the left-side toolbar
- the context menu accessible via right mouse click



Only unprocessed DICOM image series are recommended for image generation, as compressed or modified image series may result in lower-quality generated images.

7.6.1 Basic Adjustments

7.6.1.1 Brightness and Contrast

The user can adjust the brightness and contrast of the displayed images.

Using the mouse:

- Horizontal movement → adjusts brightness
- Vertical movement → adjusts contrast

Using the menu:

- “Edit” → “Brightness/Contrast”
- Toolbar icon
- Context menu accessible via right-click

When the Automatic Brightness/Contrast function is applied, the system automatically adjusts brightness and contrast based on a predefined recommendation.

7.6.1.2 Color Coding (ccDVA)

For ccDVA images, color coding represents the arrival time of the contrast agent.

- Red: early arrival
- Blue: late arrival

The start and end points of the color scale can be adjusted in the “Brightness/Contrast” menu.

7.6.1.3 Pixel Shift

The Pixel Shift function is used to reduce motion-related artifacts.

Usage:

- Select the Region of Interest (ROI)
- The system performs correction within the selected area

Pixel Shift types:

- Pixel Shift: basic motion correction
- Fixed-Size Pixel Shift: correction using a predefined ROI
- Automatic Flexible Pixel Shift: correction applied to the entire image



The Automatic Flexible Pixel Shift tool was specifically designed to improve visualization in lower-extremity examinations.

7.6.2 Special Modes

7.6.2.1 Split Mask Mode

The image can be divided into two separate regions, allowing independent ROI selection for each side. This feature is particularly useful for bilateral examinations (e.g. lower-extremity studies).

The system processes the two sides independently and subsequently combines the results into a single output image.

7.6.2.2 Anatomical Background Mode

The Anatomical Background Mode enables visualization of anatomical structures (e.g. bones) in the

background of the generated image.

This feature may assist in anatomical orientation and interpretation by providing additional structural reference information alongside the vascular visualization.

7.6.3 Image Manipulation Tools

The software provides additional image modification functions:

- Zoom In / Zoom Out
- Crop
- Sharpen
- Apply / Remove Color Coding
- Allows color coding to be applied to a selected region of grayscale-generated images and enables removal of previously applied color coding.
- Undo / Redo Modifications (Ctrl + Z / Ctrl + Y)
- Annotation

Allows annotations to be added to full-resolution images. After entering the desired text, the user can place an arrow and text box on the image by holding down the left mouse button and dragging the cursor. Once all annotations have been positioned, right-clicking allows the current DICOM image to be saved with the annotations included. If the image is not saved, the annotation text boxes will be discarded.

Notes:

- The color coding function is available only for DVA image types.



The Sharpen function is an image enhancement tool; however, repeated application does not result in significant additional image quality improvement.

7.7 Export and Saving

The software provides functions for saving studies, exporting results, and exchanging data with external systems. Export and saving functions are available through the following interfaces:

- the “File” menu
- the left-side toolbar
- the context menu accessible via right-click

7.7.1 Saving Studies

The following saving options are available in the “File” menu:

- Save
Saves the current study to its existing location.
- Save as
Saves the study with a new name or to a different location.
- Save self-contained study as
Saves the study together with all associated files in a portable format.
- Save anonymized study as
Saves the study with personal identifying information removed.

7.7.2 Advanced File Operations

- Patient folders/remote
Opens the folders where image series are stored (for example, folders used for automatic image transfer from an X-ray system).
- Show Open DICOM File
Opens the folder containing the currently loaded DICOM file.
- Download from PACS Server
Allows images to be downloaded from a PACS server using specified search criteria.

7.7.3 Export Options

Export of processed images is available through File → Export.

7.7.3.1 DICOM Format

- Images are saved as DICOM files.
- Files may contain patient information or can be exported in anonymized form.

7.7.3.2 Image Formats

Images, videos, and full-screen captures can be exported in various formats:

- PNG
- JPG
- TIFF
- BMP
- GIF

7.7.3.3 Text Format

Images can be exported as tab-delimited text files containing floating-point intensity values for each pixel.

7.7.4 Quick Export

Quick Export as DICOM

- Images are automatically saved to the location of the original DICOM file without opening the export dialog window.

7.8 PACS Communication

The software provides communication capabilities with PACS servers, including image transfer, image retrieval, and server configuration.

7.8.1 PACS Server Management

PACS servers can be configured under:

Settings → Network and File Settings → PACS Servers

Adding a New PACS Server

- Click the “Add New” button
- Enter the following information:
 - IP address
 - Port number
 - AE Title
- Click “Save”

Editing an Existing PACS Server

- Select the desired server
- Click the “Update” button
- Modify the required settings

7.8.2 Sending Images to a PACS Server

Generated images can be sent directly to a configured PACS server.

Procedure

- Open the image series
- Generate the desired images
- Select File → Send to PACS Server

- Select:
 - the destination PACS server
 - the images to be sent
 - Click the “Send” button

After completion, a confirmation window is displayed.

7.8.3 Downloading Images from a PACS Server

The software allows image retrieval from PACS servers.

- Select “Download from PACS Server”
- Enter the desired search criteria
- Click the “Search” button

The desired image series can then be selected from the search results and loaded into the software.

7.8.4 Automatic DICOM Receiving

The software is capable of automatically receiving DICOM data from external systems (e.g. X-ray equipment).

7.8.4.1 Configuration Steps

- Open:
Settings → Network and File Settings → Network
- Enable the “DICOM Port” option
- Configure:
 - Port number
 - AE Title
- Restart the software

7.8.4.2 External System Configuration

The settings of the external system (e.g. X-ray equipment) must match the software configuration:

- IP address
- Port number
- AE Title

7.8.4.3 Operation

After successful configuration:

- Images are automatically received by the system
- The user receives a notification about the incoming data

7.8.5 Automatic Upload

The software supports automatic image upload to configured PACS servers.

- Enable the “Automatic Upload” option
- Select the target PACS server
- Configure the desired upload format

7.8.6 Important Notes

- Proper network configuration is required for PACS communication.
- PACS configuration typically requires the involvement of qualified IT personnel.
- Incorrect configuration may result in communication failures.

8 System Settings and Configuration

The software settings allow customization of system behavior according to user requirements and the needs of the clinical environment.

Settings are available under the “Settings” menu and are organized into several categories containing parameters that affect system operation.

8.1 Network and Storage Settings

The “Network and Storage Settings” menu allows configuration of the software's network communication and data storage behavior.

8.1.1 Network

The “Network” tab contains parameters required for network communication.

The user can configure:

- the port number used for DICOM communication
- the ports used for HTTP communication

These settings determine how the software communicates with external systems (e.g. imaging equipment and PACS servers).

8.1.2 Remote Computers

The “Remote Computers” tab allows the addition of other computers connected to the same network.

The purpose of this function is to support:

- access to network devices
- data connectivity between multiple workstations

The configuration allows image series and data to be accessed from other systems.

8.1.3 PACS Servers

The “PACS Servers” tab is used to manage PACS connections for image storage and transfer.

The user can perform the following actions:

- add new PACS servers
- edit existing configurations
- delete PACS servers
- save settings

Proper PACS server configuration is required for image transfer and retrieval.

8.1.4 Automatic Upload

The “Automatic Upload” function allows generated images to be automatically uploaded to a selected PACS server.

Configuration steps:

- enable automatic upload
- select the destination PACS server
- configure the upload format

This function reduces the need for manual export and accelerates workflow execution.

8.1.5 Automatic Restart

The software provides configurable automatic restart functionality.

The user can configure:

- scheduled restart at a specific time
- restart after a prolonged period of inactivity

The purpose of this function is to maintain software stability and eliminate potential non-visible

operational issues that may accumulate during extended operation.

8.1.6 Storage Cleanup

The “Storage Cleanup” function allows automatic deletion of old and unnecessary files.

The user can configure:

- automatic deletion of files older than a specified number of days
- automatic deletion of log files older than a specified number of days

This function helps optimize available storage capacity.

8.2 Personal Settings

The “Personal Settings” menu allows users to create custom profiles by combining different processing and display parameters.

Profiles enable software behavior to be adapted to specific user preferences or clinical workflows.

Created profiles can be selected from a drop-down list and modified at any time.

8.2.1 Creating and Modifying Profiles

Several options are available for creating profiles:

- Clicking “New” creates a profile with default settings and allows the user to assign a custom name.
- The “Save As New Profile” function saves the current settings as a new profile while preserving the original profile.

This enables parallel use of multiple configurations.

8.2.2 Managing Profiles

- The selected profile can be freely edited by modifying its settings.
- The “Delete” button removes the selected profile from the system.

- The “Restore Settings” button resets the profile to its default values.

8.2.3 Important Notes

- Settings modifications apply only to the currently selected profile.
- Always click the “Save” button after making changes.
- Unsaved modifications will be lost.

The use of profiles supports workflow standardization and rapid application of reproducible configurations.

8.2.4 Input Settings

The “Input Settings” tab allows automatic control of incoming image series processing, display, and storage.

Automatic Generation (Network Transfer): When enabled, image generation starts automatically when a new image series is received over the network.

OR View: When enabled, the OR View is automatically opened during processing of incoming image series.

Automatically Save Generated Images and Videos: Automatically saves generated images and videos after image generation has been completed.

Automatic Selection of Contrast-Containing Frames: Automatically selects image frames containing contrast agent.

Automatically Display Rollback View in Control Room During Automatic Generation

Displays the rollback view automatically when automatic generation is performed.

8.2.5 Output Settings

The “Output Settings” tab allows configuration of generated image and video types as well as related processing and display parameters.

The configuration determines which outputs are generated and how they are processed.

8.2.5.1 Generated Images and Videos

The user can select which image and video types should be generated.

Available options:

- DVA1 Image
The default processed image type available for all supported examinations.
- DVA2 Image
An image generated using additional processing steps that may improve visualization quality.
- Color-Coded DVA Image (ccDVA)
Displays contrast arrival timing using color coding.
(Required for generating color-coded videos.)
- Cumulative DVA Video
Displays contrast flow as a cumulative time-based visualization.
(Required for generating color-coded DVA videos.)
- Color-Coded DVA Video
Displays contrast movement and arrival timing dynamically using color coding.

Selected options directly affect processing results and generation time.

8.2.5.2 Automatic Settings

The software supports automatic application of various post-processing functions.

Automatic Image Enhancement

- Automatic Brightness/Contrast for DVA Images
Automatically optimizes image brightness and contrast.
- Automatic Sharpening for DVA1 Images
Enhances image detail and visual sharpness.

- Automatic Brightness/Contrast for Grayscale Images

Provides separate optimization for non-color-coded images.

Parameter Fine-Tuning

Users can manually define baseline values:

- Contrast (slider)

Controls the intensity difference within the image.

- Brightness (slider)

Controls overall image brightness.

These values serve as starting parameters for automatic processing.

ccDVA and Video Settings

- Automatic Adjustment of ccDVA Images/Videos

Automatically optimizes color-coded outputs.

- Automatic Brightness/Contrast for Cumulative Videos

Improves video visualization quality.

Additional Automatic Functions

- Automatic Anatomical Background Selection

Defines which image type should be displayed as the anatomical background.

- Automatic Zoom When Blend Area Obscures the Region of Interest

Automatically zooms into relevant image regions when partially obscured.

These functions are intended to optimize image presentation.

8.2.5.3 General Rules

This section controls the global behavior of generated outputs.

- Automatic Inversion of Grayscale DVA Images and Videos

Applies image inversion to improve visualization.

- Anatomical Background Visibility

Controls background visibility using a percentage value.

- Default Left and Right Image Types

Defines which image types are displayed by default in the left and right result panels.

8.2.6 OR View

The “OR View” settings allow configuration of the visualization environment for real-time image display during procedures.

8.2.6.1 Display Screen

- Select Display Monitor for OR View

The user can specify on which monitor the OR View should appear. The monitor number can typically be determined from the Windows display settings.

8.2.6.2 Automatic Opening

- Open OR View Automatically at Application Startup

Automatically opens the OR View when the software starts.

8.2.6.3 Previous Result Handling

- Allow Restoration of Images Generated from Previous Image Sets

Enables reloading of previously generated images.

- Restored Image Type

Defines which image type is displayed when restoring previous results (e.g. DVA1).

8.2.6.4 Default OR View Display

- Default Left Image in OR View (Biplane)

Defines which orientation (frontal/lateral) is displayed on the left side.

- OR View Image/Video Type

Defines the default image or video type displayed in OR View.

8.2.7 Show/Hide Buttons

The “Show/Hide Buttons” settings allow customization of the user interface by controlling the

visibility of function-specific controls.

Users can enable or disable individual buttons using checkboxes.

Customizable interfaces:

- Main Window
- OR View

8.2.8 ICM/CO2

The “ICM/CO2” settings allow automatic recognition of the contrast agent type (iodinated contrast media – ICM or carbon dioxide – CO2) and automatic selection of the corresponding processing profile.

The software can identify the contrast agent type based on incoming DICOM information and automatically apply the appropriate processing workflow.

8.2.8.1 Automatic Profile Switching

The user can configure automatic profile switching based on DICOM metadata:

- Switch Automatic Generation to ICM Mode (DICOM Tag: IODINE)
Applies the ICM processing workflow when iodinated contrast media is detected.
- Switch Automatic Generation to CO2 Mode (DICOM Tag: CARBON DIOXIDE)
Applies the CO2-specific processing workflow when carbon dioxide is detected.

8.2.8.2 Handling Missing or Ambiguous DICOM Information

Default Profile Selection

If the required DICOM tag is missing or does not contain interpretable information, the system applies a predefined default profile.

8.2.8.3 Modifying DICOM Tags

Users may customize the DICOM fields used for contrast agent identification:

- Modify ICM DICOM Tag
- Modify CO2 DICOM Tag

8.3 Warning Management

The “Warning Management” menu allows configuration of warnings displayed by the software.

The user can define under which circumstances warning messages should be displayed during operation.

The software performs various validation checks during image processing and data handling.

When potentially incorrect or non-optimal input is detected, the system displays a warning message.

9 Maintenance and Uninstallation

9.1 Maintenance

The Kinepict Medical Imaging Tool does not require regular user-performed maintenance. However, the following recommendations should be followed to ensure proper system operation:

- It is recommended to restart the computer periodically. Alternatively, automatic software restart can be configured in the Settings menu to help maintain long-term system stability.
- Proper configuration of automatic file deletion settings is recommended to prevent stored patient data and image files from exhausting available storage capacity.
- For automatic deletion, a retention period of 30–60 days is generally recommended, taking local data management regulations into consideration.

9.2 Software Uninstallation

The Kinepict Medical Imaging Tool can be removed using the standard Windows software uninstallation procedure.

- Uninstallation Steps
- Open the Control Panel.
- Select Programs and Features.
- Locate Kinepict Medical Imaging Tool in the list of installed applications.
- Click Uninstall.
- Follow the on-screen instructions to complete the uninstallation process.

During uninstallation, the software is removed from the system. Certain user data or saved files may remain in their designated storage locations.

10troubleshooting and Support

For questions or issues encountered while using the Kinepict Medical Imaging Tool, please contact us at support@kinepict.com or use the “Send Feedback or Report a Problem” function. The Frequently Asked Questions section may also provide useful information.

10.1Feedback or Problem Reporting

Click “Help” → “Feedback / Problem Report” to report a software issue, submit feedback, or provide comments regarding the Kinepict Medical Imaging Tool.

Complete the form with the required information.



Ensure that any attached images are anonymized and do not contain patient information before submitting feedback.



Never share patient-identifiable information with Kinepict Health Ltd.

10.2 Incident Reporting

In accordance with applicable medical device vigilance requirements, any serious incident related to the device must be reported to the manufacturer and to the competent authority of the country in which the user and/or patient is located.

Kinepict Health Ltd.

support@kinepict.com

H-2092 Budakeszi, Kelta köz 5.

Hungary

+36 31 782 3748

National Center for Public Health and Pharmacy (Hungary)

H-1051 Budapest, Zrínyi u. 3.

Hungary

+36 1 886 9300

10.3 Frequently Asked Questions (FAQ)

The Kinepict Medical Imaging Tool has undergone extensive testing to ensure a high level of quality and reliability. If you experience a problem, please contact us at support@kinepict.com.

Alternatively, hospital IT personnel may be able to resolve the issue using the Frequently Asked Questions section.

I installed the Kinepict Medical Imaging Tool, but it does not start.

- Reinstall the software by carefully following the steps described in the **Installation** section of this Instructions for Use.
-

How can I obtain the machine identifier required for installation?

- Use one of the two methods described in the License Request section to obtain the machine identifier.
-

I forgot my username/password for logging into the software.

- This information cannot be recovered. Please create a new account using the “Registration” option.
-

The Kinepict Medical Imaging Tool is running slowly. What could be the reason?

- Verify that the computer meets the minimum system requirements. Better hardware may improve performance.
- Check your computer specifications.
- If you need assistance, please contact us at support@kinepict.com

The DICOM file does not open after selection.

- There are three ways to open DICOM-related data:
 - Open DICOM File(s): Opens a single DICOM file.
 - Open Study: Opens a previously processed Kinepict study file (.kps).
 - Open Folder: Opens DICOM directories containing related individual image files.
 - Using an incorrect option may result in an error message.
-

Some DICOM files do not open using the “Recent Files...” or “Recently Received Files...” options.

- These functions only open DICOM files that contain an image series.
 - Use the “Open Folder” option to open image series that are stored as separate DICOM files on a frame-by-frame basis.
-

Why can I save only in .kps format?

- The Kinepict Medical Imaging Tool workspace can only be saved in the Kinepict study format (.kps).
 - To save results in DICOM, image, or text format, use the “Export” function from the File menu.
-

How can I save and export my results in anonymized format?

- Click the corresponding anonymization icon to save the original files in anonymized DICOM format.
- To anonymize exported files, use File → Export and select the anonymized export option.
- To anonymize a Kinepict study file (.kps), anonymize the DICOM file before opening it in the software.

I receive pop-up messages too frequently. Can I disable them?

- Select the “Do not show again” option when the warning message appears.
 - Alternatively, warning messages can be managed in Settings → Warning Management.
-

11 Appendix

L-SOP010-002 Installation Checklist - Software Module

Name	Institute	Title	
Topic			Check
Set 'Preferences', 'Personal preferences' and 'Warning preferences' as they will be set for patient examination.			
Optionally, generated image should be sent back onto display in OR.			
Angiography Device (DICOM type, DICOM port) specifics.			
Hospital network specifics			
Is PACS upload immediate? Is there anything that could hinder file transfer to Kinepict Medical Imaging Tool? Is there anything the site IT can do about it?			

I hereby confirm that I received every essential information, I was able to ask all my questions and I am fully able to handle the Kinepict Medical Imaging Tool with responsibility.

Date:

Sign:

12 Related Publications

1. Szigeti K., et al. (2014). IEEE Transactions on Medical Imaging, 33, 2031–2038.
2. Alizadeh H., et al. (2022). Academic Radiology. DOI: 10.1016/j.acra.2022.05.007.
3. Gyánó M., et al. (2019). Radiology, 291, 246–253.
4. Thomas S., et al. (2022). Journal of Vascular and Interventional Radiology, 33, 104–112.
5. Gyánó M., et al. (2020). CardioVascular and Interventional Radiology, 43, 1226–1231.
6. Óriás V., et al. (2019). Investigative Radiology, 54, 428–436.
7. Lucatelli P., et al. (2023). CardioVascular and Interventional Radiology, 46(5), 635–642.
8. Óriás V., et al. (2020). European Journal of Radiology Open, 7, 100288.
9. Gyánó M., et al. (2021). Scientific Reports, 11, 21790.
10. Sótonyi P., et al. (2023). Journal of Cardiovascular Development and Disease, 10(5), 198.
11. Rose A. (1953). Journal of the Optical Society of America, 43, 715–716.