

viedoc™

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# Release Notes

## Viedoc 4.95

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List of functionalities that have been added and updated in this release.

## New and updated functionality

### Viedoc SDV Manager

A new application, Viedoc SDV Manager, is introduced. For all new studies added after this release, SDV settings are managed in Viedoc SDV Manager instead of in Viedoc Designer. This allows users to create SDV plans independently of design versions. Existing studies continue to use their current SDV configuration. Access to Viedoc SDV Manager is controlled by permissions configured in Viedoc Designer.

SDV plans configured in Viedoc SDV Manager allow more precise targeting of items than before. SDV requirements can be targeted not only to a form and item, but also to specific events and activities:

- RepeatKeys can be used to target, for example, the first adverse event registered for a subject.
- Items can be configured to require SDV, allow optional SDV, or to be excluded from SDV.

Different rules can be applied based on subject status, for example screening failures compared to enrolled subjects. Multiple SDV plans can be configured, saved, and published within a study. Plans can also be exported and imported.

SDV plans can be assigned to one or more sites by effective date. A different plan can be assigned to a site when the site risk level changes. This enables different SDV strategies to be applied across sites and over time, which supports risk-based monitoring approaches.

Viedoc SDV Manager can also be enabled for ongoing studies. When enabled, all existing SDV requirements in Viedoc Clinic that were configured in the study design are removed. New SDV plans must then be created in Viedoc SDV Manager to define the new SDV requirements in Viedoc Clinic. Previously performed SDV in Viedoc Clinic is retained.

Note that enabling Viedoc SDV Manager for an ongoing study cannot be undone.

### Viedoc Designer

- A new section has been added to the roles configuration page for Viedoc SDV Manager permissions. The following permissions are available:
  - View plans
  - Create/edit plans
  - Publish plans
  - View plan assignments
  - Assign plans to sites

# Release Notes

## Viedoc 4.95



List of new and updated functionalities continues.

A new role, SDV Manager, is available in Viedoc Designer. This role includes all of the above permissions by default and is intended for users managing the full SDV plan lifecycle. The View plans and View plan assignments permissions are enabled for the default Monitor role. All permissions can also be assigned individually to other roles.

- A dedicated subject status for screening failure is introduced. As with other subject statuses, the study designer can now define screening failures in the subject status settings. The screening failure status is included with the other subject statuses in the performance section in Metrics, in SDV Manager and in the “subject status” dataset in the data export. Note! Viedoc Reports will continue to use the existing derivation for calculating screening failures, that is, “subject is withdrawn, but not enrolled”, on the dashboard and in standard reports. In a future release, the new screening failure status will be implemented in Viedoc Reports. Existing custom reports are not affected by this change, however the new screening failure status will be available for use in custom reports after the release.
- There have been several improvements made to the PDF generation for the Configuration Report, forms, and workflow, resulting in increased performance. To improve readability in generated PDFs and form representations:
  - Spacing between items within the same item group has been increased.
  - The **Choose one** option is now included in lists where applicable (previously this option was not shown).
  - The order number of code list items is now displayed in a badge.
  - Footer text is displayed in a different font color.

### Viedoc Clinic / Viedoc Designer

Added support for DICOM de-identification during upload. Users can upload ZIP archives with DICOM files, automatically remove PHI (HIPAA/DICOM Part 15 tags), and apply pixel masking. Non-DICOM files are rejected. De-identified files are uploaded as a new ZIP, are downloadable, and follow the standard file upload flow with audit history.

### Viedoc Coder / Viedoc Designer

Viedoc Coder now supports medical coding with items in repeating item groups, including combinations of terms and supporting values across repeating and non-repeating groups. Viedoc Designer provides validation when configuring scopes and design versions:

- A warning is displayed for unsupported configurations, while still allowing publishing. Unsupported configurations may result in unusable coding scopes or excluded items.
- Validation ensures compatibility with the new Coder while warning against use with the legacy coding console.

Items within repeating groups are now correctly handled in exports.

# Release Notes

## Viedoc 4.95

### Bug fixes



List of bug fixes that have been updated in this release.

This section lists the bugs that were solved in this release. For each bug, it describes the following:

- **Affected area(s):** describes briefly which area(s) of Viedoc the bug is related to, so that it is easy to identify if any of your active studies are affected.
- **Bug description:** explains the issue and/or how it was solved. In case there are consequences for existing data, this is clearly mentioned in a "Note!".

The following corrections have been implemented in the Viedoc 4.95 release:

- **Affected area(s):** Viedoc Clinic  
**Bug description:** After the Viedoc 4.94 release, the Add new event dialog in Clinic failed to load the event list for studies with unscheduled event names containing an apostrophe or other special characters. For example, if an unscheduled event had the name "Doctor's visit", selecting Add new event on a subject resulted in an empty event dropdown being displayed. This has now been solved so that the Add new event dialog opens correctly regardless of special characters in event names.
- **Affected area(s):** Viedoc Clinic  
**Bug description:** In rare cases, if a user updated information in user settings without saving the changes, the user remained logged in. This has now been solved by ensuring that the inactivity logout always overrides the unsaved changes warning.
- **Affected area(s):** Viedoc Clinic / Viedoc Reports  
**Bug description:** In large studies with many sites and large amounts of data, exports and Viedoc Reports data updates could occasionally fail or take a long time to complete. This has now been solved so that data is processed separately for each site before being combined into the final result. This reduces the risk of failures and improves reliability for exports and Viedoc Reports data syncs in large studies. The exported content and sort order remain unchanged.
- **Affected area(s):** Viedoc Coder / Viedoc Clinic  
**Bug description:** Data exports that include medical coding history fail if any item change is attributed to the Viedoc system user. This has now been solved by including the Viedoc System user GUID in the runtime dictionary of expected user GUIDS.
- **Affected area(s):** Viedoc Admin  
**Bug description:** After the Viedoc 4.94 release, translated texts in non-Latin scripts (such as Japanese and Chinese) appeared nonsensical in the section for the randomization method in the randomization configuration in Viedoc Admin.

# Release Notes

## Viedoc 4.95



List of bug fixes continues.

- **Affected area(s):** Viedoc Designer  
*Bug description:* When a user signed in to Viedoc with one user account and then changed to a different user account, the previously logged-in user's information and study list was displayed in Viedoc Designer instead of the newly signed-in user. This has now been solved, so that Viedoc Designer now correctly reflects the currently signed-in user information even when changing user accounts.
- **Affected area(s):** Viedoc Me  
*Bug description:* After submitting forms in Viedoc Me, participants could select the Back button in the browser to navigate to the data entry screens of submitted forms. The data appeared editable, but updates could not be submitted because the form could not be submitted again. This has now been solved. Participants cannot navigate back to the data entry screens after submitting the form. This fix does not apply to legacy Viedoc Me.
- **Affected area(s):** Viedoc Me  
*Bug description:* When participants clicked the "Next" button multiple times in quick succession, in rare cases, they could unintentionally skip multiple screens and miss questions. This only occurred when consecutive screens contained item groups of identical length, causing the "Next" button to appear in the same position on each screen. This has now been solved by introducing a brief cooldown period after screen transitions, which prevents the "Next" button from being activated immediately upon arriving at a new screen.
- **Affected area(s):** Viedoc Me  
*Bug description:* When participants were forced to change the PIN upon first login, they could reuse the PIN that was initially generated. This has now been solved. Participants are prevented from using the same PIN again when being forced to set a new PIN.
- **Affected area(s):** Viedoc Me  
*Bug description:* When forms with free text fields and paragraph texts were saved in Viedoc Me, long text strings entered by the participant were truncated in the form PDF. This has now been solved, so that the full text is displayed in the PDF. Existing PDFs are not affected by this change. In Viedoc Clinic, and in export formats other than PDF, all data was displayed as expected. PDFs created in legacy Viedoc Me were not affected.
- **Affected area(s):** Viedoc TMF  
*Bug description:* In the TMF Records listing, date and time columns, for example, Uploaded to drop zone datetime and Uploaded to Viedoc TMF datetime, could appear in different formats within the same Excel export. This has now been solved so that all date and time columns in the TMF Records Excel export use a consistent format aligned with the old Viedoc TMF UI.

# Release Notes

## Viedoc 4.95



List of bug fixes continues.

- **Affected area(s):** Viedoc TMF  
*Bug description:* When attempting to move a file with spaces or special characters in the filename (for example, &, #, %, or +) from the Drop zone to an Artifact, the action failed with a BadRequest error and could result in a partially saved file requiring manual correction. This has now been solved, so that files with valid filenames, including special characters, can be moved from the Drop zone to an Artifact as expected. Documents can now also be previewed, downloaded, and filtered in the Records section regardless of filename characters.
- **Affected area(s):** Viedoc Reports (PMS Dashboard)  
*Bug description:* For PMS studies, in Reports, on the PMS Dashboard, in the “by Subject” subreport, the “% Frozen” column incorrectly had sorting and filtering enabled. This was not intended behavior, as sorting and filtering for this column should be disabled. This has now been solved, and sorting and filtering is now disabled for the “% Frozen” column in the “by Subject” subreport and is therefore now consistent with the PMS Dashboard “by Site” subreport. The standard report continues to display correct data.

# Release Notes

## Viedoc 4.95

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## Known limitations



Constraints that define Viedoc's current capabilities, distinguishing its intended scope from defects or bugs.

Please visit Known Limitations page which describes system-wide and application-wide constraints that may affect your study setup and operations.

You can access the Known Limitations page at the following URL:

<https://help.viedoc.net/c/331b7a/5e2a11/en/>

# Release Notes

## Viedoc 4.95

### Signoff



Signature Confirmation by  
the product manager.

Signed by:  
*Royden James*  
CB50F38D3AE440C...  
2026-05-25 | 14:22 CEST

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Envelope Sent	Hashed/Encrypted	5/25/2026 2:21:06 PM
Certified Delivered	Security Checked	5/25/2026 2:21:12 PM
Signing Complete	Security Checked	5/25/2026 2:22:38 PM
Completed	Security Checked	5/25/2026 2:22:38 PM
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