



# Release Notes

## Viedoc 4.65

Available for users on  
2021-04-29

# Release Notes

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### New functionality



List of new functionality that has been added to this release.

This release introduces the following new feature in Viedoc:

- In Viedoc Clinic and in Viedoc Admin, there is now a user administration log report in Excel format, containing a log of the roles and users in the study with access and certification information.

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### Updated functionality and bug fixes



List of functionality and bug fixes that has been updated in this release.

#### Updated functionality

- In Viedoc Designer, there is now a Repeating action available on the Alert setup page, making it possible to configure the system to send alerts repeatedly to users at a defined interval.
- In Viedoc eTMF, a maintenance mode is introduced in the Admin interface which enables editing and deleting sections, zones, and artifacts in instantiated structures.
- In Viedoc eTMF, a new function is introduced: users with review permission can now lock and unlock a finalized document to prohibit as well as enable the possibility to perform changes on that document.
- For Viedoc eTMF, the eLearning now contains a new lesson, *Viedoc-provided templates*, with links to templates for non-device and device studies that can be downloaded and adjusted according to your study needs.
- In Viedoc Reports, the “Reason for withdrawal” plot can now display data collected from checkbox items.
- In Viedoc Reports, there is now extended settings for customizing the color palette according to different user accounts, to make it easier to distinguish between them.
- In ViedocMe, Danish is now available as a system language.

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List of functionality and bug fixes continues.

### Bug fixes

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

- **Affected area(s):** describes shortly which area(s) of Viedoc the bug is related to, so that it is easy to identify if any of your active studies is 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 4.65 release:

- **Affected area(s):** Form history PDF in Viedoc Clinic  
**Bug description:** Sometimes in the form history PDF, the form header showed up on the first page with a page break causing the rest of the table to appear on second page. This is now solved.
- **Affected area(s):** Export preview in Viedoc Clinic  
**Bug description:** The columns for the Y-axis were filtered to include only number data type. This is now solved, and it is possible to select dropdowns and radio buttons as value for the Y-axis as long as the values are non-decimal, positive numbers (including 0).
- **Affected area(s):** Date format from Viedoc API  
**Bug description:** The date format for 100% enrollment was returned in different formats depending on instance, system, or study setting. The web API response for date format for this value will now always return in ISO 8601 format (YYYY-MM-DD).
- **Affected area(s):** Translation in ViedocMe  
**Bug description:** When changing the PIN code, the text “PIN code” was not translated. This is now solved.
- **Affected area(s):** Polish translation in ViedocMe  
**Bug description:** The Polish translation was not correct after the changing PIN code in ViedocMe. This is now solved.
- **Affected area(s):** Forms in Viedoc Clinic  
**Bug description:** When opening a form containing a checkbox with a function returning an invalid value, an “Action not accepted” message was shown. This is now solved.
- **Affected area(s):** Country codes in Viedoc Reports  
**Bug description:** When several sites have the same site code defined in Admin, Viedoc Reports was listing subjects with the wrong country code, causing the plots to show incorrect data. This is now solved by adding the country code as a prefix to the site code, so that subjects located at sites with the same site code are kept separated.

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List of functionality and bug fixes continues.

- **Affected area(s):** Review status report in Viedoc Reports  
**Bug description:** In some cases, if SDV was not part of the study scope, the Review status report was not rendered for any status. This is now solved.
- **Affected area(s):** Launching Viedoc Reports  
**Bug description:** If the visibility settings in Global design settings are not completed, the initial data sync will not work, and Viedoc Reports will not launch. This scenario is now clarified to the user with an error message and is also logged in the data sync log.
- **Affected area(s):** Data sync in Viedoc Reports  
**Bug description:** Many studies had their data sync time at 10 pm and the sync lasted for more than 2 hours. Consequently, studies with sync time at 11pm was disrupted and the data sync was delayed until the next day. This is now solved.

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## Known limitations



List of limitations that have been found with this and earlier releases of Viedoc, and will be changed in future releases.

The following limitations exist in this release of Viedoc:

### Viedoc Clinic

- Edit/enter data
  - For scheduled and unscheduled events, when the visit date form (\$EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a visit includes the \$EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or visit). If you sign forms on a visit individually you will not be able to sign the \$EVENT form. This in turn makes it so that the sign symbol that appears on the visit when everything is signed does not appear, even though it looks like everything is signed.
  - When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.
  - It is not possible to delete unscheduled visits if automatic visit dates are enabled.
- File upload
  - For security reasons, it is not allowed to upload executable files. The complete list of unsupported file types can be found in Viedoc 4.34 Release Notes.
  - The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- Layout
  - When adjusting the font size in a form item this is not respected by Internet Explorer 11. This may result in a change to the layout of the form. The descending sorting in the subject list view is not working properly.
- Subject list
  - The descending sorting in the subject list view is not working properly.
  - When clicking to sort a column containing dates in the subject list view, Viedoc sorts all dates using a numeric variant of US date representation (for example, 1977-NOV-16 comes before 1967-DEC-16 because the first is sorted like 11/16/1977 and the latter is sorted like 12/16/1967).
- Data export
  - The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.

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List of known limitations continues.

- PDF export
  - Visit date form history will not be included in PDF export if no forms were filled in, or if forms were initiated from ViedocMe.
  - When using Windows 7, filenames added to the zip archive during PDF export get scrambled when they contain Unicode characters. The extracted file content is not affected by this. There is a Hotfix for Windows 7 available at: <https://support.microsoft.com/en-us/kb/2704299> that addresses this issue.
  - PDFs generated upon form save in Viedoc versions prior to 4.51 were generated and stored based on the role visibility conditions applied to the user that last saved the form. Items that were hidden to the user due to role visibility conditions are not shown/included in such generated PDFs.
  - Fully PDF/A compliant archives are only supported if all the included form PDFs and study event PDFs were generated on, or, after 2017-03-10 (Viedoc 4.33). It is still possible to generate PDF/A compliant archives that contain form and study event PDFs generated before this date, but you might receive warning messages related to PDF transparency issues.
  - In the PDF/A export output, the header, footer, and the text on the respective Contents page are missing for the deleted forms/events/subjects.
- CSV export
  - The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (for example, an OID defined as AE in design version 1 and ae in design version 2).
  - Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
- Data review
  - The SDV task count, the green checkmark and the issue list on the subject Selection page do not take role visibility into consideration. This means that if forms or items are hidden to a certain clinic role, it might look as if there are still tasks to be performed, even if the user with that role does not have access to perform these tasks (due to visibility conditions).
  - Queries of the type “Required value missing” responded with “Confirmed as missing” and cannot be rejected by the sponsor side.
  - A field that is required for SDV but is hidden on a form (due to for example visibility conditions) can normally not be marked as having been verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.
- Issues and task
  - The Issue list will not be visible for sites that have more than 1000 subjects.

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List of known limitations continues.

- **Metrics**
  - The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with state “Removed”.

### **Viedoc Admin**

- **User management**
  - Any of the Organization Administrator, Organization Designer, and Site Manager roles that were removed from a user are not listed in Viedoc Admin, under User Settings > Studies and Roles.
  - When sorting studies by group and generating a “User and Roles” or “User Administration Log” report, the Download link is not exposed for the newly generated file until the page is refreshed.
- **Data import**
  - It is only possible to import values (choice numbers), not strings (choice labels), when importing data into data fields where multiple checkboxes can be checked.
- **ODM import/export**
  - It is not possible to import an ODM file that was exported from Viedoc including the Event Dates into Viedoc Admin. The following error message is displayed: “An item with the same key has already been added”.
  - Only one (selected) design can be imported from each CDISC ODM file.
  - ODM export fails when subject data contains large, uploaded files.
- **Apply revision**
  - The affected forms count shown in Viedoc Admin while applying a study design revision is implemented only for production sites. Demo/Training site forms are not included in this count.

### **Viedoc Designer**

- **General**
  - Viedoc Designer is not working properly in Internet Explorer 11.
- **Validation of study design**
  - Validation of alerts, selection view settings, event visibility, subject status condition, common event summary format and subject ID generation settings for deleted items is not performed.



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List of known limitations continues.

- **Item settings**
  - For the code list items (checkboxes, radio buttons, dropdown), it is possible to set the same code list values for multiple choices within the same item. This is not recommended. Unique code list values should be used for each of the choices within the same item.
- **Study workflow**
  - When the Event ID for the Study Start event contains the word “START”, including combinations with other words and punctuation, and scheduling other events based on the Study Start event, this results in an error. The workaround is to use a different ID for the Study Start event, one that doesn’t contain the word “START”.
- **Roles and permissions**
  - If the role that has the permission for Emergency unblinding also has a role visibility condition that makes the blinded outcome hidden for this role, the outcome gets hidden for all roles after unblinding, and not just for the role specified in Viedoc Designer.
- **Visibility conditions**
  - When creating forms for ViedocMe, visibility conditions can only include variables that have already been introduced, and that are in the same form and on the same page. This behavior differs from the one in forms for Viedoc Clinic.
- **Edit checks**
  - Edit checks are not triggered on dates when the event date is used as default value, and the calendar picker is used to choose the date.
  - Using \$THIS inside a form to refer to an item within a different instance of the same form, does not work, as it always refers to the same form instance. This is true when referring to an item in the same form within another activity, or when referring to another form instance within the same activity (applicable for repeating forms).
  - If two scheduled events have the same event date, and both events contain a form with a function or data check that uses the \$PREV function, the \$PREV functions in these two events refer to each other as the previous event, and not to the event that occurred earlier in the study workflow. This creates a circular reference and makes it impossible to refer to earlier event(s).
- **Alerts**
  - If the condition for an alert is set within a form for which the option to auto-update functions is enabled, and the alert is triggered, the alert message will be sent twice.

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List of known limitations continues.

- Form and workflow PDF
  - If, in the Study Workflow, there are more activities with the same activity name within the same event, then the forms in these activities are incorrectly displayed in the Bookmarks list in the study workflow PDF. Please note that only the Bookmarks list is affected, the events/activities/forms are correctly displayed within the document.
  - The PDFs generated as Empty CRFs will not display all code list items for radio buttons, drop-down lists and checkboxes if these have been configured with many code list items in a vertical layout.

### Viedoc API

- The API method SubmitData allows submitting data into a form that exists in the effective design but does not exist within the respective event according to the study workflow. In such a case, a new form is created and added to the event.

### ViedocMe

- If additional languages are imported (to be used in ViedocMe) and after that code lists are combined via “Formats” (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
- For ViedocMe translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content, before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated ViedocMe form).

### Viedoc Logistics

- In the exported stock list, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.

### Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.
- Viedoc Reports is currently available in English only.
- Viedoc Reports is not supported on the sponsor side in Japanese PMS Studies.
- Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.

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List of known limitations continues.

### **Viedoc eTMF**

- Viedoc eTMF is currently available in English only.
- Viedoc eTMF is only running in Production mode.
- In Viedoc eTMF maintenance mode, when making changes to the structure of an artifact, all documents within the artifact is affected as follows:
  - All documents are shown as updated by the system in the Trial Master File view.
  - All published documents, except locked documents, change the status to “flagged by QC” with no audit trail or comment.
  - Documents with status “awaiting review” change status to “flagged by QC” with the old comment.

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### Signoff



Signature Confirmation by  
the product owner.

**Uppsala, Sweden 2021-04-22**

**Andreas Hedlund**

Viedoc Technologies