

Release Notes

Viedoc 4.44

Available for users on
2018-08-26

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Updated functionality and bug fixes



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

Updated functionality

- The pop-up that shows the pending invitations and the *Access Settings* pop-up were modified so that the pending invitations and the current roles are displayed separately, in different pop-ups, as follows:
 - All the pending invitations are displayed in the *Pending invitations* pop-up that is automatically displayed after login, and where you can accept/reject each invitation.
 - The *Access Settings* pop-up displays only the list of the current roles you have in Viedoc, where you can remove roles, as well as view the login history.
- In Viedoc Admin, it is now possible to sort (ascending/descending) the user lists in *Study crew* and *Site users* views, by:
 - *User* (default)
 - *Role*
 - *Since*
 - *Status*
- The notification email for the approval of study deletion was updated to include the study Reference ID.
- In the signing console, the *Sign all* link for signing all forms in all visits for a subject was moved from the pop-up header to a separate row, for usability purposes.

Bug fixes

This section lists the bug that were fixed in this release, for each bug describing the following:

- **Affected studies/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 that was fixed and how the system worked before the bug fix. In case there were consequences on existing data, this is mentioned as well in a “**Note!**”

The following corrections have been implemented in this release of Viedoc:

- **Affected studies/area(s):** Related to the ODM import in Viedoc Admin for sites in demo mode.
Bug description: In Viedoc Admin, importing an ODM file by selecting the “Import to demo” option was not working.

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List of bug fixes continues.

- **Affected studies/area(s):** Related to the user and roles PDF report.
Bug description: In some scenarios with many users having system roles, the user and roles PDF had some formatting problems.
- **Affected studies/area(s):** Studies using medical coding.
Bug description: When trying to code a value that contained HTML tags, for example <paracetamol> (note the angle brackets), the code was not applied. This is now fixed, and it is possible to apply codes to values containing HTML tags.
- **Affected studies/area(s):** Related to the counter of incorrect password in the signing console, see description below.
Bug description: The counter for the number of times a user has entered the wrong password was not reset after entering the correct password in the signing console.
- **Affected studies/area(s):** Related to the SDV status.
Bug description: A double click/submit on SDV resulted in the review flags being set wrongly on item level (that is displayed in the export output). The review flags were still correct at the form level.
Note! If your study was affected, you will be contacted by a Viedoc representative.
- **Affected studies/area(s):** Studies with visibility conditions at activity level and where revision(s) were approved by site personnel.
Bug description: When a change to the CRF structure was approved by the site personnel on the *Message* page, with changes on item(s) hidden at activity level (in study workflow), the SDV on form level was broken even for those forms included in the activities where the updated item was hidden.
- **Affected studies/area(s):** Related to items set as hide always in a revision, see description below.
Bug description: For an item set as hide always in a revision, the item values were reset while editing and saving the form after the revision was applied.
Note! If your study was affected, you will be contacted by a Viedoc representative.
- **Affected studies/area(s):** Related to items set as hide always and checked/unchecked at activity level, see description below.
Bug description: The hide always setting was overridden by the item visibility settings on activity level, i.e. if the item visibility settings were changed in the study workflow under *Item visibility*, and the item was also set as *hide always*, it was still visible in Viedoc Clinic (even if it should have been hidden as per hide-always setting). This is now fixed, so that an item set as hide always is not visible in Viedoc Clinic, regardless of the item visibility settings in the study workflow.
Note! If your study was affected, you will be contacted by a Viedoc representative.

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List of bug fixes continues.

- **Affected studies/area(s):** Studies with alerts configured.
Bug description: In the alert emails, the URL displayed in the footer (that identifies the server instance) was not correct. This is now fixed.
- **Affected studies/area(s):** Related to site users listing.
Bug description: A Site Manager who also had a Helpdesk role could not see any users listed, except for himself/herself, under *Site Settings* in Viedoc Admin.
- **Affected studies/area(s):** Related to the filename of the *User and roles* PDF report.
Bug description: There was a minor spelling error in the filename of the *User and roles* PDF report that is now fixed.
- **Affected studies/area(s):** Related to the Reference Data.
Bug description: Populating the reference data values in Viedoc Clinic was not working for the radio button items.
- **Affected studies/area(s):** Related to the Close form button when using an iPad.
Bug description: The *Close* button for all forms in Viedoc Clinic was not visible when using an iPad device in portrait mode. Note that the button was accessible and working properly in landscape mode, though.

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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:

- Uploading password protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- 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* document.
- Only one (selected) design can be imported from each CDISC ODM file.
- The PDFs generated as Empty CRFs will not display all code list items for radio buttons, dropdown menus and checkboxes if these have been configured with many code list items in a vertical layout.
- A field that is required for SDV but is hidden on a form (due to for example visibility conditions) cannot normally 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.
- The affected forms count summary shown in admin while applying a study design is implemented only for production sites. Demo/Training site forms are not included in this summary count.
- 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.
- The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
- 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, file names 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.
- The PDFs generated upon form save will be 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 will not be shown/included in the generated pdf.
- The Issue list will not be visible for sites that have more than 1000 subjects.
- The task count includes tasks for hidden forms.

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List of known limitations continues.

- The Issue list does not take role visibility into account.
- 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.
- 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.
- 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.
- The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (e.g. an OID defined as **AE** in design version 1 and **ae** in design version 2).
- Checkbox items with choices having long text set in Viedoc Designer might not be shown properly in Viedoc Clinic. The choice text might be truncated and not completely visible although it looks good in Viedoc Designer. The problem is also visible in the form preview in Viedoc Designer, which shows an identical form as what the users will see in Viedoc Clinic. Therefore, make sure you always check the form preview after designing a form to make sure that everything looks as expected.
- In Viedoc Clinic, on the subject selection page, the SDV task count, the green checkmark, as well as the issue list do not take into consideration role visibility, meaning that, if for example forms or items are hidden to that Viedoc Clinic role, it will still appear that there are tasks to be performed even if the user does not have access to perform those (due to visibility conditions).
- Labels are truncated to 200 characters when csv data is imported to SAS using the CSV2SAS macro.
- Fully PDF/A compliant archives are only supported if all the included form/study event pdfs were generated on or after 2017-03-10 (Viedoc 4.33). Generating PDF/A compliant archives that contain form/study event pdfs generated before this date will still work but might have warnings related to transparency.
- 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.
- Using \$THIS in in any type of expressions inside a form to refer to an item within the same form but a different activity within the current event always refers to the same form instance where the function is executed, i.e. the current activity.
- The API method **SubmitData** allows submitting data to a form that exists in the effective design but not within the respective event according to the study workflow. In such a case, a new form is created and added to the event.

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List of known limitations continues.

- 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 importing, in Viedoc Admin, an ODM file that was exported from Viedoc, the following error message is displayed: "Following users do not have email id: SYSTEM". This can be fixed by manually removing the SYSTEM user entry from the xml file.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2018-08-19

A handwritten signature in blue ink, appearing to read "Andreas Hedlund".

Andreas Hedlund

PCG Solutions