

Release Notes

Viedoc 4.38

Available for users on
2017-11-23

Release Notes

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Updated functionality and bug fixes



List of functionality that has been updated in this release.

Updated functionality

- Reference ID – a valid Reference ID is needed to be able to set a study from demo mode to production mode. A study is in production mode once the first site is set to production. After the study is set to production mode, the Reference ID is being locked and there is no way to unlock it afterwards.
- Data import – it is now possible to set character encoding in data import application, by using the `<FileEncoding>` tag.
- Data import – It is now possible to set delimiter in the data import application, by using the `<FileDelimiter>` tag.

Note! Please note that you need to download the latest version of the data import application in order to be able to use the new features. The download link is available in Viedoc Designer under Global design settings > Data mapping. Please contact your Viedoc representative in order to get an updated version of the Viedoc Data Import Application document.

Non-functional updates

- Medical coding – changed dictionary name from WHO DD to WHODrug.
- ViedocMe – changed term from *Questionnaires* to *Events*, in order to align the terminology with the one used in Viedoc Clinic.

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List of bug fixes.

Bug fixes

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

- Description of the bug, explaining how the system worked before the bug fix and how it is working after the issue was fixed.
- *Possible consequences for active studies:* This describes the impact the respective issue and/or the fix might have on active studies.
- *Check this in your study:* Depending on the possible consequences on active studies, if there are things to consider to be verified on existing data or configuration, this is described here. If there is no need for this, then this will be not applicable (N/A).

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

- The user having a role with the user rights set to *User can only view form data (this overrides all edit permissions)* was still allowed to add a new subject in Viedoc Clinic and to initiate a visit. This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- When clearing the value of a text item in Viedoc Clinic, it remained an empty string and it was not set to NULL. This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- In ViedocMe the tooltip for the user name was displaying “PIN code”. This is fixed now as the tooltip is removed and only the user name is displayed.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- Performance improvements for Viedoc Clinic and ViedocMe for studies with many events.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- “Missing reason approved” message is replaced by “Answer approved” when saving a form with missing data.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.

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List of bug fixes continues.

- All expressions (in visibility conditions, functions, edit checks) are now always executed based on the respective study site time zone.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- In forms with the “auto update functions” option checked, the visibility conditions were not evaluated automatically and thus items becoming hidden when re-executing the function(s) were not reset. This is fixed now, and the visibility conditions are being validated for these forms when a function is re-executed.
Possible consequences for active studies: the affected studies will be identified, and all the affected clients will be contacted by a Viedoc representative to discuss any further action needed for their study.
Check this in your study: the affected studies will be identified, and all the affected clients will be contacted by a Viedoc representative to discuss any further action needed for their study.
- For forms with the “auto update functions” option checked, the form status (such as missing fields) was not updated after the function was auto updated (due to dependency change). This is now fixed.
Possible consequences for active studies: Forms with the “auto update functions” option checked might have incorrect status, the status will be correctly updated the next time the auto update form is saved (either by manually saving or when the function is auto updated).
Check this in your study: N/A.
- For forms with the “auto update functions” option checked, the edit checks were not re-validated when the function was auto updated (due to dependency change). This is now fixed, and edit checks are validated each time a function is re-executed resulting in a new value.
Possible consequences for active studies: Forms with the “auto update functions” option checked might have incorrect edit check status, the edit checks will be correctly run the next time the auto update form is saved (either by manually saving or when the value of an auto update function changes).
Check this in your study: N/A.
- In ViedocMe the form could be registered multiple times in case of a double submission. This is now fixed and the double submission is prevented so that the form is sent out only once.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.

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List of bug fixes continues.

- Proposed date calculation, as well as the timing for reminders, was not calculated correctly for events related to subject initiated events. This is now fixed so that proposed date calculation and reminder timing are calculated correctly and use only the date part (no time) of the event they are dependent on.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- The data import application crashed when trying to import a file that was not accessible (being locked by another instance of the data import application or in progress of being uploaded). This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- New audit records were created for items confirmed as missing for each form save after the one in which they were confirmed as missing the first time. This resulted in incorrect date and time being displayed for the confirmed as missing operation as the date and time of the latest audit record was displayed. This is now fixed, so that items confirmed as missing will not receive a new audit record unless they are edited and thus the correct date and time is shown for new edit operations performed in Viedoc 4.38 and onward.
Possible consequences for active studies: Because of the bug, the items confirmed as missing in Viedoc versions older than 4.38 have the date of the last form save and this might be different than the date when they were confirmed as missing for the first time.
Check this in your study: N/A.
- For the checkbox items with visibility conditions, in ViedocMe these were still visible when they were supposed to get hidden based on the visibility condition. This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- An unexpected error during the add subject process could lead to incomplete subjects being created. This is fixed now, so that if any error occurs during add subject, the whole action is canceled, and the user is prompted with an error message and allowed to try again.
Possible consequences for active studies: Because of the bug, there might be subjects that were added to the study in Viedoc versions older than 4.38 for which the add subject form cannot be open.
Check this in your study: Incompletely created subjects were identified and all clients affected were contacted to discuss any further action needed for their study.

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List of bug fixes continues.

- For date items saved with only year and month, the last audit record was shown in format yyyy-mm-dd in the audit trail. This is now fixed, so that only month-year is shown in the audit trail if no exact date is chosen.
Possible consequences for active studies: The audit trail is now displayed correctly in the “Show history” view even for the data filled in in Viedoc versions older than 4.38. Still, the problem remains in the “Form history” pdf files that were generated in Viedoc versions older than 4.38.
Check this in your study: N/A.
- After adding an item group with a visibility condition in a design revision, the form was shown wrongly in view mode as the added item group was visible although the condition evaluates to false. This is now fixed, so that the visibility conditions are validated when adding item groups with visibility conditions in a revision.
Possible consequences for active studies: In forms for which the design was revised and an item group with a visibility condition added, the form might be shown wrongly in view mode as the added item group will be visible although the condition evaluates to false. Note that the form will not be marked with having an issue and the item group will be hidden as soon as the user enters edit mode.
Check this in your study: N/A.
- Under certain circumstances, the export to excel was not working when including the *Review status*. This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- If in the study design, under *SDV Settings* only certain forms and items were selected, and in a design version some items were deleted, the export was not working for the respective study. This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.
- The export to PDF was not working for locked studies set to demo mode. This is fixed now.
Possible consequences for active studies: This does not affect active studies.
Check this in your study: N/A.

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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.
- Deletion of a common event is shown with the form name in strikethrough instead of the summary format details.
- 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.

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Known limitations



List of known limitations continues.

- The Issue list will not be visible for sites that have more than 1000 subjects.
- The form history view does not display all form versions when bulk upgrade has been performed, however all form versions are correctly stored in the database.
- The task count includes tasks for hidden forms.
- 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).
- SAS import fails if exported data contains forms that were populated using a reference data scope. This is due to the fact that the reference data scope GUID (*Globally Unique Identifier*) is included in the export output and this is not recognized by SAS. The workaround is to rename it to a SAS compatible variable name in the file to be imported.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2017-11-20

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