June 2022

Release Note: QIAcuity® Software Suite

Dear valued customer,

The following changes were made in the QIAcuity Software Suite version 2.1.7.182. Beside of usability improvements and bug fixes, the new features address GMP requirements by offering additional support for 21 CFR part 11 compliance, copy number variation (CNV) analysis, support of future Nanoplates, and improved 1D scatterplot views.

New features

- Customizable user management

  o Option to add additional roles and to assign permissions, individually. Users may then be assigned to these new roles offering a fully flexible and customizable user management.

  o List views for all existing roles, permissions, and users assigned to a selected role.

- Additional permissions

  o New plate ownership permissions to restrict access to plates. Plate ownership is now mandatory in version 2.1. Plate ownership will be kept during upgrading, restoring, importing, exporting, and archiving of plates.

  o New permission allowing deleting reports in case they are not yet signed. Signed reports cannot be deleted.

- Audit trail

  o Improved report handling tracking such as signer name, date and time of signature, plate ID, and a unique report ID

  o Improved user management activity tracking such as creation of new roles and assigning permissions to roles

  o Improved user logging event tracking such as user name, date and time, instrument ID, and logging event (log on, log off, log on failure, as well as automatic log off)

  o Audit Trail status indicator at the QIAcuity Software Suite status line

  o Clearing of instrument errors will now be tracked.

- Signatures

  o Introducing an electronic signature functionality. Signing reports require downloading of the report, proving user credentials, and a reason for signing the report. User name, date of signature, and signing reason will be included in the report.

- Cyber security improvements

  o User accounts are blocked for 10 min after 3 unsuccessful login attempts.

  o Increased requirements for the strength of passwords. Now requires to be 8 characters or more, at least one upper and one lower case letter, one number, and one symbol.

  o Each password will expire after 30 days and have to be renewed. Please read the user manual for version 2.1 for more information.

o Introducing password protection at multiple sites to increase cyber security

Improvements

- Additional option to for CNV analysis

    o New analysis offering CNV calculation based on a reference target without the need for a separate reference sample

    o Allowing the selection of multiple targets of interests for one reference target

- 1D scatterplot

    o Improved visualization of 1D scatterplots for QIAcuity 26k plates to address artifacts related to the image acquisition

- Usability

    o New functionality for searching plates by barcodes

    o Adding an option to post a comment for creating a report

    o Introducing a report ID ensuring each report can be clearly identified

    o Adding information about date and user creating a report in the report list view

    o Option to include plate ownership in the report

- Data export functionalities

    o New compact CSV export option for RFU values with reduced file size

    o Files generated by the RFU CSV export and the RFU compact CSV export now include the reason for the invalidation of partitions

- Backup during upgrade

    o A data backup plan for the upgrade have been introduced into the software installer of version 2.1.

- Future Nanoplate support readiness

    o Implementation of labware files for upcoming QIAcuity Nanoplate 26K 8-well.

- Algorithm improvements

    o Improvements to remove artifacts reference channel such as significant brightness differences within bigger areas

    o Improved dust detection, for example, for diffuse dust

    o Minimizing the effect of scatter light effecting the crimson channel and improving signal-to-noise ratio.

    o Improved auto-threshold for 26k Nanoplates to increase reliability of the threshold in case of an outlier threshold of a single subwell

Bug fixes

- Fixed certificate handling to overcome network connection issues observed in version 2.0

- Fixed an error that occurred in case the login page was opened and no credentials were entered

- Improved behavior in 2D scatterplots where a visual artifact was observed after the lasso tool has been used to assign double positives to single positives

- Fixed an issue that resulted in a loss of the barcode information after a plate had been upgraded from version 1.2 to version 2.0 of the QIAcuity Software Suite

- Fixed an error in the archive search functionality that prevents finding updated plates which names including the prefix "copy"

- Fixing the display of values in mutation analysis in case the mutation frequency is 0

- Option for multiple occupancy within "Export to CSV" is no longer visible when only 1 channel or 1 target was selected

- Fixing an issue related to the "Save plate" functionality when user changed the plate layout

- Included validation of entries made by users in "Create new user" form to avoid conflicts within the software

- Stability improvements for upgrade and installation of software version 2.1

Known issues

- In some cases, the channels chosen in the QIAcuity CSW are not correctly displayed in the QIAcuity Software Suite. This, however, does not affect the analysis.

- In case the QIAcuity Software Suite is opened at multiple browser windows or browser tabs and an error message is given at on browser tab, it will be automatically shown on all opened windows and tabs and sometimes duplicated in browser tab currently used/selected. This does not have any effect on the results and the messages may be closed.

- In case a plate is restored from starting from plate information page, the spinner indicating that the software is restoring a plate is not shown. This has no effect on the plate data. To avoid this issue, please start restoring plates using the 3-dot menu.

- If a user aborts a run on the instrument, the plate status changes to "Run Aborted," but no details are shown. These details can be found in the Instrument CSW GUI as long as the plate is loaded in the instrument.

- When an upgraded plate has been deleted, the original plate tile is not updated until the browser page is refreshed.

- When a plate is imported or restored from QIAcuity Software version 1.2 or older, the information of the original version is not shown.

- When a plate is about to be imported into a QIAcuity Software Suite and a plate with the same name already exists, a wrong message (Error 409) is shown. Instead, the message "Cannot import plate because this plate already exists in the system. To be able to import this plate, duplicated plate needs to be removed from the system" (Error 400) should be shown.

- When searching for plate names in the Archive, special characters such as !@# cannot be searched for. When a password is tried to be renewed and the same password is entered, a wrong message is shown, saying that "The user password couldn't be changed due to the problem with server connection. Contact your administrator to solve this issue". This message may be ignored, and a new password can be entered which is different to the one previously used.

Updating the instrument software

For the update from version 2.0.20, a backup option of the QIAcuity database has been introduced. Please remember to delete the backup file after successfully installing version 2.1.7.182.

Caution: A direct update of the QIAcuity Software Suite version 1.1.3 to 2.1.7.182 is not possible. Please follow the instructions in the user manual for updating to version 1.2.18 first before updating the QIAcuity Software Suite to 2.1.7.182. Not following the instructions may result in a loss of your previous plate data.

Visit **www.qiagen.com** and go to the Software section of the QIAcuity product page to check for the latest QIAcuity Software Suite version and the latest user manual. On a computer running Microsoft® Windows®, download the software update. Locate the "QIAcuitySuite.msi" file and double-click it. The installation process starts. Follow the instructions given in the User Manual.

Note: Only users with an Administrator role can perform software updates.

Note: The latest QIAcuity Software Suite version 2.1.7.182 is only compatible with the QIAcuity CSW version 2.1.0.41. If only one software component is updated, no connection between the QIAcuity Software Suite and CSW can be established.

Important: It is strongly recommended to update the QIAcuity Software Suite first before proceeding with the update of QIAcuity CSW.

The QIAcuity Software Suite is designed to work with Windows 10 Professional Edition version 1809 OS Build 17763.1697 or higher. The following browsers were tested in the QIAcuity Software Suite:

- Mozilla® Firefox®: version 100.0.1

- Microsoft Edge: version 101.0.1210.47

- Google Chrome®: version 101.0.4951.67

Best regards,

Your QIAGEN Team