

Cc: To the Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities

26 July 2019

Urgent Field Safety Notice: QIAsymphony SP, Ref: 9001297 - Software 5.0.3

Dear QIAsymphony customer,

We would like to inform you that we have identified a specific issue that you might come across on your QIAsymphony. This issue has been observed **only** in QIAsymphony software version 5.0.3 when using the 2D bar code integration feature with continuous loading of the QIAsymphony SP. Continuous loading is when additional batches are defined and assigned to the same elution rack as a batch that has already been started.

Description of the issue

When performing a multi-batch run using continuous loading in combination with the 2D bar code integration functionality, an incorrect 2D bar code assignment can be made to samples within the SP results file. The associated rack file for the run is not affected by this issue. It contains the correct 2D barcode assignments so there is no loss of traceability tracking.

The Sample ID assigned during QIAsymphony batch definition and the position of the eluate on the elution rack are not affected.

Potential Risks Associated with the Issue

The results file for the first run are correct. Subsequent runs will have the incorrect 2D barcode eluate ID assigned for each sample (see Figure 1). If 2D bar code eluate IDs are not checked against the sample ID prior to downstream application, the incorrect tube may be selected and it could lead to delayed results or incorrect patient reporting.

Actions to be Taken by the Customer/User:

Discontinue use of the workflow in the following specific conditions:

QIAsymphony software version 5.0.3 when using the 2D bar code integration feature with continuous loading.

Please note that the 2D bar code labware, continuous loading, and Software 5.0.3 can still be used independently of the integration feature.

If you believe you may have been affected by this issue, please see below for advice on how to detect and resolve any mis-assignments.

Detection of Affected Batches

If you suspect that your runs may be affected, this issue can be easily detected using the HTML version of the SP results file.

In the "Detailed Information for Batch" section of the SP results file, the Sample ID entered at QIAsymphony batch definition and the assigned 2D barcode can be seen. The data in the Sample ID column is a combination of both identifiers created for reporting purposes. The Sample ID has not been changed.

In the example shown below, it can be seen that the 2D bar code value has been correctly assigned to samples 1 - 8 for the first batch (2000318). In the second batch (2000319), the 2D barcode values have been repeated from the first batch and incorrectly assigned to samples 9 - 16.

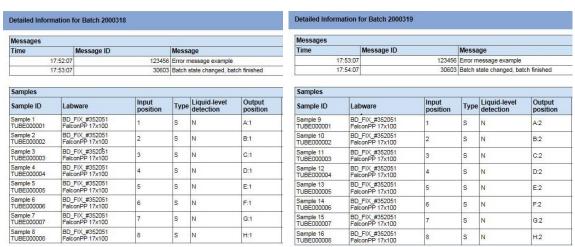


Figure 1 Results File

In the event that a run has been affected, the correct 2D bar code assignments can be obtained from the rack file. The rack file is in an XML file but can be opened in Microsoft Excel to provide a table as shown below.

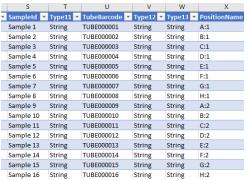


Figure 2 Rack File viewed in excel

QIAGEN's commitment to resolving the issue

QIAGEN recognize that this issue may impact your workflow and we are working to address it in a software

update and it will be communicated as soon as possible.

IMPORTANT NOTE TO IMPORTERS, DISTRIBUTORS, and COMMERCIAL PARTNERS

Please quarantine your QIAsymphony SP inventory with the software version 5.0.3. Serial Numbers **35437** and higher are pre-installed with software version 5.0.3. Please also notify your customers with this letter

and request acknowledgement accordingly. QIAGEN will contact you with further instructions

Completion of the Acknowledgement of Receipt form

To ensure that all affected users are notified and according to applicable national statutory provisions, we

are obliged to provide proof of notification in the market to the authorities. Therefore, please complete and

sign the included Acknowledgement of Receipt form and email it to QIAGEN Technical Services at

techservice-eu@qiagen.com or fax it to +49 (0)2103-29-22400.

We regret any inconvenience caused by this situation. If you have further questions, please contact QIAGEN

Technical Services Department.

Please visit the following webpages for contact information:

QIAGEN Subsidiaries: https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/

• QIAGEN Commercial Partners and Importers: https://www.qiagen.com/about-us/contact/global-

contacts/distributors-and-importers/

Best Regards

Your QIAGEN team

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QIAsymphony SP, Ref: 9001297 – Software 5.0.3 Acknowledgement of Receipt form

(Please complete form using block letters)

I hereby acknowledge that I have received, read and understood the included Urgent Field Safety Notice described above. We have taken the necessary actions as suggested by this notice:

- The information was forwarded to all individuals and departments within our organization using this product. The notice was forwarded to the end user.
- We reviewed this notice with our laboratory/medical director.
- For commercial partners only: This notice was forwarded to our customers.
- For commercial partners only: We ceased the distribution of the affected products. We followed-up on the Acknowledgements of Receipt with our customers.

Laboratory/Company name:	
Instrument serial number(s):	
Please confirm the discontinued use of the 2D bar code function with continuous loading?	
☐ YES DATE:	\square N/A (not using the 2D barcode with continuous loading)
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date: