June 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.

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Managing Directors: Peer M. Schatz, Roland Sackers, Dr. Barthold Piening

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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.

Detailed Information for Batch 2000318

Messages

Time	Message ID	Message
17:52:07	123456	Error message example
17:53:07	30603	Batch state changed, batch finished

Samples

Sample ID	Labware	Input position	Type	Liquid-level detection	Output position
Sample 1 TUBE000001	BD_FIX_#352051 FalconPP 17x100	1	S	N	A:1
Sample 2 TUBE000002	BD_FIX_#352051 FalconPP 17x100	2	S	N	B:1
Sample 3 TUBE000003	BD_FIX_#352051 FalconPP 17x100	3	S	N	C:1
Sample 4 TUBE000004	BD_FIX_#352051 FalconPP 17x100	4	S	N	D:1
Sample 5 TUBE000005	BD_FIX_#352051 FalconPP 17x100	5	S	N	E:1
Sample 6 TUBE000006	BD_FIX_#352051 FalconPP 17x100	6	S	N	F:1
Sample 7 TUBE000007	BD_FIX_#352051 FalconPP 17x100	7	S	N	G:1
Sample 8 TUBE000008	BD_FIX_#352051 FalconPP 17x100	8	S	N	H:1

Detailed Information for Batch 2000319

Messages

Time	Message ID	Message
17:53:07	123456	Error message example
17:54:07	30603	Batch state changed, batch finished

Samples

Sample ID	Labware	Input position	Type	Liquid-level detection	Output position
Sample 9 TUBE000001	BD_FIX_#352051 FalconPP 17x100	1	S	N	A:2
Sample 10 TUBE000002	BD_FIX_#352051 FalconPP 17x100	2	S	N	B:2
Sample 11 TUBE000003	BD_FIX_#352051 FalconPP 17x100	3	S	N	C:2
Sample 12 TUBE000004	BD_FIX_#352051 FalconPP 17x100	4	S	N	D:2
Sample 13 TUBE000005	BD_FIX_#352051 FalconPP 17x100	5	S	N	E:2
Sample 14 TUBE000006	BD_FIX_#352051 FalconPP 17x100	6	S	N	F:2
Sample 15 TUBE000007	BD_FIX_#352051 FalconPP 17x100	7	S	N	G:2
Sample 16 TUBE000008	BD_FIX_#352051 FalconPP 17x100	8	S	N	H:2

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.
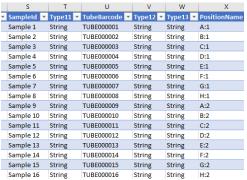
	S	T	U	V	W	X
	SampleId	Type11	TubeBarcode	Type12	Type13	PositionName
	Sample 1	String	TUBE000001	String	String	A:1
	Sample 2	String	TUBE000002	String	String	B:1
	Sample 3	String	TUBE000003	String	String	C:1
	Sample 4	String	TUBE000004	String	String	D:1
	Sample 5	String	TUBE000005	String	String	E:1
	Sample 6	String	TUBE000006	String	String	F:1
	Sample 7	String	TUBE000007	String	String	G:1
	Sample 8	String	TUBE000008	String	String	H:1
	Sample 9	String	TUBE000009	String	String	A:2
	Sample 10	String	TUBE000010	String	String	B:2
	Sample 11	String	TUBE000011	String	String	C:2
	Sample 12	String	TUBE000012	String	String	D:2
	Sample 13	String	TUBE000013	String	String	E:2
	Sample 14	String	TUBE000014	String	String	F:2
	Sample 15	String	TUBE000015	String	String	G:2
	Sample 16	String	TUBE000016	String	String	H:2

Figure 2 Rack File viewed in excel

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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.

<u>IMPORTANT NOTE TO IMPORTERS, DISTRIBUTORS, and COMMERCIAL PARTNERS</u>

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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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:** _____ ☐**N/A** (not using the 2D barcode with continuous loading)	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date:

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