



TITLE: FIELD SAFETY NOTICE TEMPLATE

RESPONSIBLE DEPARTMENT: RAQS MANAGEMENT

STATUS: **CURRENT**

DOCUMENT No. **F-GP010-002**

ISSUED: **10<sup>TH</sup> NOV 2017**

VERSION: **2**

## Urgent Field Safety Notice

Commercial name of the affected product: see 2019\_DK\_FSCA.xlsx attached

FSCA-identifier (e.g. date): QMS-446

Type of action: advice of action to be taken by the user

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Date: 7<sup>th</sup> Feb 2020

Attention: to whom it may concern

### Details on affected devices:



### Description of the problem:

Due to a random manufacturing failure, in rare cases (0,2%) the indices of an adapter plate can be rotated by 180°. This failure is easily detectable – as described below at the advice section -, so it has no consequences on the health of patients, but it may cause a slight delay in treatment management and inconvenience for the user. The failure was already fixed by our manufacturing site to eliminate recurrence in the future.

### Advise on corrective actions to be taken by the user:

In cases where adaptor plates A, B or C are used, the failure can be easily detected by reviewing the positive and/or negative controls that were included the run according to accreditation standards. Customers observing a failure, can fix it by re-queuing the fastq file generation on the Illumina instrument using a corrected Sample Sheet. This can be achieved using the Omixon Workbook by re-ordering the sample numbers 1 to 96 in the order 96 to 1 when generating the Sample Sheet.

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In cases where adaptor plates A1, A2, A3 or A4 are used, the failure can be detected by visual inspection of the adaptor plate before use, since columns 10, 11 and 12 would be filled, as opposed to columns 1, 2 and 3. If the adaptor plate is used in a "rotated" way, the same fix as above (re-queuing the fastq file generation with a corrected sample sheet) may be implemented to obtain the correct results.

**Please acknowledge upon receipt that you are aware of the content of this Field Safety Notice by sending back attached 'Acknowledgement of FSN\_QMS\_446' document completed, signed and dated.**

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Peter Meintjes  
CEO  
Omixon Biocomputing Ltd  
Fehérvári út 50-52.  
1117 Budapest  
Hungary  
[support@omixon.com](mailto:support@omixon.com)

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Signature

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