Urgent Safety Information

Recall on AION Software Update- version v3.0.1

21.12.22

Sender
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Addressee
Users of AION software with version v3.0.1

Reference
NG-A-FSCA2022-1

Product version
AION v3.0.1

Information
AION CE-IVD software version v3.0.1 has been upgraded to improve its clinical performance and operating efficiency. During AION routinary maintenance two potential occurrences that could affect software performance and yield suboptimal results were identified and treated as non-conformances which triggered the corrective actions and changes that lead to a new software version v3.1.0 deployment. Problems identified related to: 1) AION variant classification based on ACMG criteria (bug-caused miscalculation error), which in some cases could cause a genetic variant pathogenicity misclassification (e.g. incorrectly labeling variants which should be classified as “Pathogenic” and “Likely pathogenic” as “Variant of Unknown Significance (VUS)” instead); and 2) to AION architectural design obsolescence affecting the upload and running of the VCF input data. Occurrences identified herein were subjected to risk assessment and considered as critical and potentially having an impact on software performance efficiency and decreased clinical performance. Upon root cause analysis, corrective/preventive actions consisted of a new version of AION software v3.1.0 including:

- Software patch released to fix the bug affecting ACMG variant classification calculations restoring optimal values.
- ACMG variant classification was upgraded by implementing new criteria based on PS2, PVS1, PM2, PM3, and PM6 to improve software clinical performance.
- Software frontend architecture refactoring which prevents data input files from being rejected or stuck in processing, facilitates problem solving actions and supports the upload of larger VCF input files.

Recommended actions for the user
AION is a cloud-based software intended to be used by genetics professionals only in a healthcare setting. Affected customers using the v.3.0.1 version were identified and informed immediately. Additional analysis services were performed by Nostos Genomics' technical team and customer support to guarantee optimal performance of clinical cases.
If we have not contacted you in this regard, you do not need to take any further action.

Passing on the information described here
Please ensure in your organization that all users of AION v3.0.1 and other persons to be informed are made aware of this Urgent Safety Information.

Following the IVD Regulations, the Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information". AION software is CE-IVD compliant with IVDR Art. 110(3).

It is important that you read carefully and acknowledge receipt of this letter.
Please print, fill and return signed the confirmation receipt that follows this letter (page 3) by email at regulatory@nostos-genomics.com

We thank you for your attention to this matter and for your collaboration.
If you have any further questions on this topic, please contact us at regulatory@nostos-genomics.com.

Best Regards

[redacted]

Nostos Genomics GmbH

Urgent Safety Information

Feedback form

We ask you to return this feedback form to us promptly, but no later than 30 days after receipt of this letter to the following email address: **regulatory@nostos-genomics.com**. Thank you for your collaboration.

Customer ----------

Address ----------

Reference
NG-A-FSCA2022-1

Product version
AION v3.0.1

I confirm that I have received and understood the safety information related to the indicated reference and product version stated above.

Date:

Name:

Signature