FSN Ref : COMPL-304 (2000-FSN-001)
FSCA Ref : CAPA-338
Date : November, 2020

Urgent Field Safety Notice
- Veye Chest 'Volume/Growth Discrepancy'-

For Attention of*:

- Head of the Radiology department
- Any radiologist reading lung CT scans using Veye Chest

Contact details Aidence B.V.	Signatures
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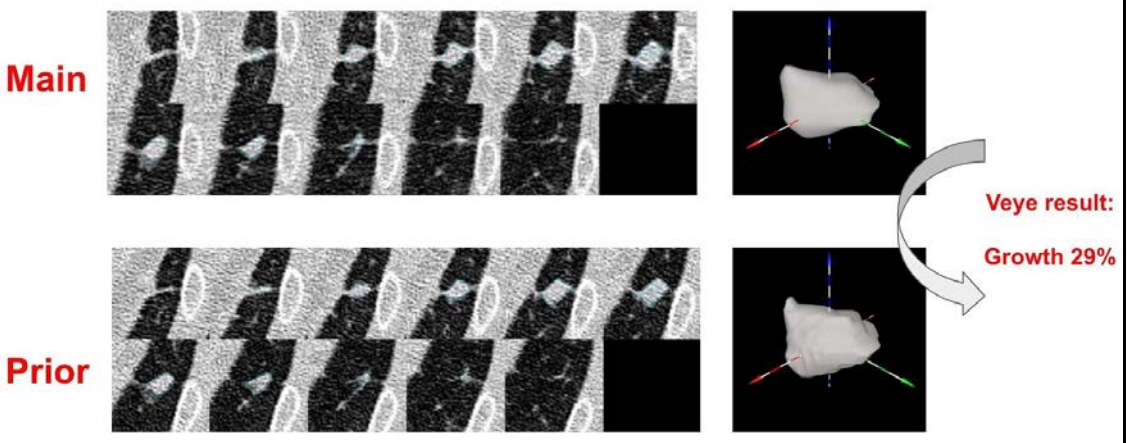
- Veye Chest -

Information on Affected Devices	
1.	**Device Type(s)**
	Veye Chest is intended to assist physicians in their review of CT scans in the detection, classification, quantification and growth assessment of solid and sub-solid pulmonary nodules using low-dose or standard-dose, and non-contrast or post-contrast scans with a maximum axial slice thickness of ≤3mm. Veye Chest is intended for use as a second or concurrent reader.
2.	**Commercial name(s)**
	Veye Chest (including Veye Reporting)
3.	**Software version(s)**
	Veye Chest version 2.0.0 up to Veye Chest 2.14.0

Reason for Field Safety Corrective Action (FSCA)	
4.	**Description of the product issue**
	Under normal operation: The quantification module of the device outputs for each candidate (potential pulmonary nodule): **1.** Per-slice **segmentation;** **2.** **Volume measurements** derived from the segmentation (1), and; **3.** **Growth measurements** (e.g. growth percentage and volume doubling time) derived from the volume of a single candidate (2) on two consecutive scans; **4.** **Diameter measurements** derived from the segmentation (1). Under normal operation, the radiologist can verify the volume measurement (2) by visual inspection of the segmentation (1). If the segmentation (1) is correct, a radiologist can assume the volume measurement (2) to correspond with the segmentation (1), and consequently the growth measurement (3) (where applicable) which is derived from volume measurements over time (2). **Under abnormal operation:** The volume measurement (2), and if applicable the growth measurement (3), can include an unexpected large variation and as a result may deviate from the displayed segmentation (1). **NOTE!** The **diameter** measurement (4) accuracy is **not affected** under the abnormal operation. Neither are the **detection** performance (sensitivity and false positive rates) and **nodule classification** performance (solid vs subsolid).

5.	**Hazard giving rise to the FSCA**
	Where there is a deviation* of the volume measurement (2) in relation to the displayed segmentation (1), this could lead to: 1. **Overestimation of the volume measurement** (as compared to the presented segmentation); 2. **Underestimation of the volume measurement** (as compared to the presented segmentation); 3. **Overestimation of growth** (as compared to the presented segmentation on the main and prior); 4. **Underestimation growth** (as compared to the presented segmentation on the main and prior); Veye Chest is intended for use as a second and or concurrent reader, however where these values would be relied upon, there is a potential risk for an incorrect follow-up of the patient in line with the clinical guidelines, which might result in: ● **Inappropriate diagnostic work-up**, such as follow-up CT, PET/CT or even biopsy; ● **Inappropriate frequency of follow-up scans,** either expedited or delayed; ● **Inappropriate discharge** of a patient who should have been followed up, resulting in a potential risk of missed early-stage lung cancer. *Internal data suggests that the vast majority of such deviations vary between 0 - 20%. Deviations of more than 10% are considered clinically relevant, and outliers have been found to go up to 30%
6.	**Predicted risk to patients**
	How often does it possibly affect patient management? Following a thorough internal analysis, we estimate that up to 4% of patients (with at least one pulmonary nodule found by Veye Chest) are affected by this discrepancy, leading to a different management decision (provided volume and/or growth from Veye Chest is used in reporting and clinical decision making). In the majority of the cases the discrepancy overestimates the volume compared to the segmentations. In addition thereto, the following risk mitigations further apply: ● Veye Chest is used as second and or concurrent reader; ● Review of the original series in the PACS will allow users to visually verify the size of a pulmonary nodule (on a main and prior scan); ● Diameter measurements of the pulmonary nodules are correct in relation to the displayed segmentation; ● The majority of variations result in overestimation rather than underestimation, reducing the chances of inappropriate discharge; Taking the above into consideration, the predicted risk to patients receiving an incorrect follow-up recommendation, or inappropriate discharge is considered **very low**.
7.	**Background on Issue**
	Aidence has become aware of this issue through a feedback case that was reported. In this feedback case, a growth of 29% was displayed by Veye Chest, however the segmentations displayed between the main and prior scan did not visually represent a growth that would represent 29% growth.

8.	**Other information relevant to FSCA**
	Example of the report that was provided to Aidence as part of the feedback case.



	Type of Action to mitigate the risk
9.	**Actions to be taken by physicians using Veye Chest** Until a fix is implemented, we strongly recommend that for each scan the user: 1. Visually verifies the accuracy of the segmentation of the pulmonary nodule; 2. If the segmentation is accurate, checks that the volume aligns with the expected volume based on diameters, using the diameter-to-volume conversion table below; 3. As the deviation can affect both the main and prior scan, make sure to perform actions 1 and 2 on the prior scan to ensure growth is accurate.

Diameter-to-volume conversion table

Largest axial diameter (mm)	Expected Volume (mm3) *(Note: broad approximation assuming a perfect sphere)*
4	30
5	70
6	100
8	250
10	500

10.	**Patient follow-up** Aidence offers all customers the opportunity to retrospectively analyse all CT scans that have been processed by the affected versions of Veye Chest. This will provide an overview of all patients that might have received an incorrect follow-up recommendation due to the issue described in this FSN.

	If a customer wishes to make use of this offer they will need to complete and submit the document "Appendix A: Retrospective Analysis Form" to Aidence before december 14th 2020.
11.	**Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection **X Software upgrade (pending)** ☐ IFU or labelling change ☐ Other ☐ None

	General Information	
12.	FSN Type	New
13.	Further advice or information already expected in follow-up FSN?	Yes
14.	If follow-up FSN expected, what is the further advice expected to relate to: - Implementation of the fix into the software	
15.	Anticipated timescale for follow-up FSN	Within 10 working days
16.	The Competent (Regulatory) Authority of your country has been informed about this communication.	

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.