

**Product** : Veye Chest 2.6  
**Aidence reference** : COMPL-163

### **Pulmonary nodule diameter rounding issue** Corrective Action of retrospectively analysed CT chest scans

#### **Retrospective impact analysis**

After the deployment of Veye Chest version 2.6 until the deployment of the fix (either in 2.7.4, or local hotfix), reported diameters of pulmonary nodules may have been rounded incorrectly. (See *Field Safety Notice COMPL-163 dated 14.11.2019* for details).

Therefore it is possible that incorrect pulmonary nodule follow-up recommendations were made based on the incorrect rounded diameters. In order to assess whether this has actually occurred, and to potentially correct the follow-up recommendation, all CT chest scans that were analysed by Veye Chest during this period need to be subjected to a retrospective analysis.

Aidence is able to execute this analysis for you. The entire process consists of four (4) stages.

***Please return a completed copy of "APPENDIX A" within 14 days to Aidence indicating which, if any, of the stages you would like to execute.***

#### **Stage 1**

Aidence will create a list of all the CT chest scans that were analysed by Veye Chest during the affected period. This will be done with a custom script written by Aidence, based on the Veye Chest database. This information will be provided to you so that you can determine the range of diameters that are at risk for incorrect follow-up recommendations, depending on the guidelines used at your site. This will provide the total number of scans potentially affected based on site-specific conditions.

#### **Stage 2**

Each potentially affected CT chest scan (excluding priors) will be re-analysed by Veye Chest without the normal response sent back to the PACS. The result of this stage is a list of CT chest scans in which findings are present that are rounded incorrectly. This results in a (shorter) list of scans that are affected by the rounding issue.

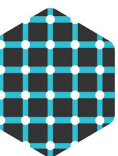
#### **Stage 3**

Each CT chest scan on the list will be subjected to a review by a radiologist in order to determine whether changing the incorrect diameter to its correct value (ie. becoming 1 mm less) would impact the nodule follow-up recommendation.

Aidence is offering to perform this clinical review under your supervision to minimize your radiologists' workload. Of course you may choose to perform such analysis yourself, or decide this is not needed.

#### **Stage 4**

For any scans where a clinical difference was detected, you will decide on appropriate follow up actions. Optionally, Aidence will support the replacement of the incorrect analysis in the site's PACS, or append a corrected analysis.



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### APPENDIX A - Retrospective Impact Analysis Form

Organisation:

Contact person:

Email address:

Phone number:

I have understood the potential impact of *Field Safety Notice COMPL-163 14.11.2019* and would like Aidence to execute the following stages of the retrospective impact analysis:

No stages

Stage 1

Stage 2

Stage 3

Stage 4

Date:

Signature:

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Please send a signed copy to:

- a) [ga@aidence.com](mailto:ga@aidence.com), or
- b) Sarphatikade 8, 1017 WV, Amsterdam, the Netherlands