

Předmět: Bug affecting Astraia Version 1.27.0 or higher with MDT
Datum: pátek 11. února 2022 16:28:19 Středoevropský standardní čas
Od: astraia Support
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Kategorie: astraia

Dear Customer,

Unfortunately we have found a bug affecting astraia Version 1.27.0 or higher, with the selection of DICOM SR values for import into astraia software

Affected astraia versions:

1.27.0, 1.27.1, 1.27.2, 1.27.3, 1.28.1

Summary of the bug:

Since astraia version 1.27.0 the item mode (*<!ATTLIST item mode (last | max | first | min | mean) "last">*) of the DICOM SR measurement transfer is not being taken into account (except for the mode ,mean') and instead ,last' is always taken as default.

The anomaly occurs if a series (>1) of measured values of one type is transferred to astraia software within the workflow of recording/transferring values for an ultrasound. ***This is the only case in which the error occurs and the version would be affected.*** If only single value of a particular type is transferred (e.g. nuchal translucency) the version is not affected.

One of the most immediate consequences is that the default configuration ,max' for NT (nuchal translucency) is not working. If a set of values of NT is transferred to astraia software for risk calculation (Trisomy 21, etc.) NOT a determined measurement value of the set according to configured mode (e.g. max value) is used, but the last value of the set evaluated by the sonographer is used.

Risk Identification and Impact:

If a series of values is transmitted and a mode is active (e.g. max) then values other than those determined by the sonographers/medical staff are transmitted to the astraia software. These values could be used for the risk calculation.

The anomaly can lead to a reduced positive predictive value which means a decreased amount of trisomies could be detected. As long as a standard configuration is in place other part of the calculation results wouldn't be affected by the nature of this risk .

Astraia software calculates the risks of Trisomy 21 [IVD], 18 and 13 according to an algorithm provided by the FMF UK (Fetal Medicine Foundation). This probability alone does not give a valid diagnosis. Only sonographers who have been certified by the Fetal Medicine Foundation, London (FMF) are allowed to perform a risk calculation with astraia software. As a result of this fact, the probability that valid values are used in the calculation of the first trimester risk is very high.

Workaround:

- Workaround 1: Check the NT measurement values before and after the transmission to Astraia software. Change the transferred value in Astraia software to the correct and determined value you want to use for the risk calculation in according to the measurement. This is already documented in astraia software manual
- Workaround 2: Manually put in the values for the risk calculation
- Workaround 3: Transfer only one value of a measurement type manually (e.g. NT.)

One of these presented workarounds must be followed to guarantee a correct calculation based on the values the sonographers determined.

Planned measures of astraia:

- A new update of astraia software, version 1.27.4, for the correction of the application misbehaviour described above is planned to be released in March 2022 for 1.27.x customers. No new installation or configuration is needed. All changes will be provided by the update.
- For the 1.28.1 customer a configuration of the ultrasound will be performed.

Note : We have already informed and filed a field safety notice with the medical regulatory body, BfArM (German health department) and other authorities of other countries, based on our CAPA Case „2022-02-02 CAPA AST-7150“ (corrective actions preventive action).

If you have customised your measurement transfer with a mode configuration, please validate them. Contact astraia Support in case you need assistance.

We would like to assure you that we would do all the needful to deal with this situation
Please don't hesitate to contact us if you have any questions.

astraia Support team

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