Customers of astraia software gmbh
with astraia software version 1.27.0 or higher

Field Safety Notice 2022-02-02 CAPA AST-7150

Dear Sir or Madam,

We would like to inform you as the user/reseller of astraia about a possible bug in transferring measurement data, used for the calculation of the aneuploid risks, from an ultrasound machine into astraia.
This safety notice has been created on the base of CAPA Case „2022-02-02 CAPA AST-7150"(corrective actions preventive action).

You will **not** be affected if you
- don't transfer measurement data from an ultrasound machine
- transfer exactly one value as NT measurement
- transfer max NT directly from the ultrasound device
- transfer the single NT value you want to use manually preselected on the ultrasound device

If none of the above applies to you then we will inform you here about
- the exact conditions that might cause the bug
- the exact measures you should take
- the steps astraia is taking to fix the bug

If you require further information or assistance in connection with this incident, please contact your local partner or the astraia support. This safety notification will also be reported to the authority responsible for your county.

We apologise for any inconvenience caused.

Dr. Uwe Hannemann
General Manager
astraia software gmbh

<u>Field Safety Notice</u>

Astraia Software Version 1.27.0 or higher

Erroneous selection of DICOM SR values for import into Astraia software

I. Affected products	All software versions of astraia software 1.27.0 or higher. All affected versions are listed in detail below:
	
	      1.27.0;
	      1.27.1;
	      1.27.2;
	      1.27.3;
	      1.28.1;
	
	Only 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 does the anomaly occur. This is the only case in which the error occurs and the version would be affected. If only single values of a particular type are transferred (e.g. N.T. = nuchal translucency) the version is not affected.

II. Failure description	If a set of values of a type (e.g. N.T.) is transferred to astraia software for risk calculation (Trisomy 21, etc.) NOT a determined measurement value of the set according to configured filter (e.g. average value) is used, but the last value evaluated by the sonographer of the set is used. **Example:** Three measurement results for N.T. are transferred to astraia software and the sonographer determined to use the average value but the last value which maybe is not the average is used for Risk calculation (FTS, T21, etc.). Value A: 2.1mm Value B: 2.2 mm Value C: 2.3 mm Average Value: 2.2 mm selected filter and determined value by sonographer Last Value: 2.3 mm actually transferred value **Steps to reproduce:** 1. Create a patient with exam. 2. Configure measurement server from astraia for operated application version. 3. Do an ultrasound and fetch the created patient record. 4. Enter values for e.g. N.T. (at least 2 values). 5. Transfer to Astraia software application. 6. Click the button "Transfer". 7. Compare the values (transferred/documented and determined).

III. Potential Risk	**Risk Hazard** Therapy or diagnosis decisions supported by astraia software are based on other measurement values than expected by the medical staff. If a series of values (>1) is transmitted and a filter is active (e.g. average) then values other than those determined by the sonographers/medical staff are transmitted to the astraia software. These values are eventually used for the risk calculation (see also I). **Risk Identification and Impact:** According to the anomaly only a lower risk for e.g. Trisomy 21 would be calculated. Other therapy treatments wouldn't be affected by the nature of the risk (see risk hazard and II.). Astraia software First Trimester Screen Module calculates the risks of Trisomy 21 [IVD], 18 and 13 according to an algorithm provided by the FMF UK (Fetal Medical Foundation). This probability alone does not give a valid diagnosis (see also intended use of medical device). Only sonographers who have been certified by the Fetal Medicine Foundation, London (FMF) are allowed to perform a risk calculation with astraia software First Trimester Screen Module. As a result of this fact, the probability that valid values are transmitted to astraia software is very high. **Risk Probability** If a set of values is transferred to astraia software for documentation and/or risk calculation the probability depends on the amount of values and the filters configured by the medical facility.
IV. Identification of affected products	It has been tested in different versions and was found only for the product versions listed under item I. of this document. An evaluation of the CRM database with all distributed and affected product versions has been made and all affected customers according to this evaluation have been notified.
V. Necessary measures of the affected customers	• Workaround 1: Check the 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 according to the measurement. • Workaround 2: Manually put in the values for the risk calculation. • Workaround 3: Transfer only one value of a measurement type (e.g. N.T.). One of these presented Workarounds must be followed to guarantee a correct calculation based on the values the medical staff determined.
VI. Planned measures of astraia	• A new release of astraia software including a patch for the correction of the application misbehaviour described above (see II.) is planned to be released in March 2022. • Support the customers of affected versions. The patch will be an update for the affected installed version. No new installation or configuration is needed. All changes will be provided by the patch/update.
VII. Further information and support	If you require further support and information in this context, please contact your local partner or support of astraia.