May 9, 2019
May 16, 2019 Rev1

To: Whom It May Concern

ARKRAY Factory, Inc.

Urgent Field Safety Notice
AUTION HYBRID AU-4050 FSCA

We thank you for your patronage of our products.

Regarding the Fully Automated Integrated Urine Analyzer AUTION HYBRID AU-4050, it was found that incorrect patient information is linked and reported when the certain conditions overlaps. Therefore, we determined to implement FSCA (a voluntary correction) after notifying to the regulatory authorities

We apologize for any inconvenience this may have caused you, and your understanding and kind cooperation for the correction would be highly appreciated.

1. Product and Program version to be corrected:

Distribution Name: AUTION HYBRID AU-4050 (Code 14602) All Serial numbers

Program version Ver.00-03 ~ Ver.00-16

2. Details of Defect

It was found that when all the following conditions overlap, the patient information under the condition (1) (patient name, patient ID, date of birth, gender, etc.) was erroneously linked to the analysis result under the condition (3) and reported. For the sample number and measurement result, correct information is reported.

Condition (1): After inquiring the FCM order to the host, the certain errors occurred and one of the following events occurred.
- No analysis order from CHM to FCM
- FCM analysis was stopped by error.

Condition (2): Turn the Main Unit power off without shutting down the IPU.

Condition (3): Item Rack(s) was used for analysis.

*When both Main Unit and IPU are shutdown, the patient information data is deleted each time, therefore, incorrect patient information is not obtained.

* The Instruction Manual indicates that both the Main Unit and the IPU should be shut down per "4.6 Shutting down the instrument". In this case, Condition (2) is not applied and the defect doesn't occur. However, the Instruction Manual indicates that only the Main Unit should be shutdown only for "8.8.4 Cleaning or replacing the sample filter".

3. Estimated Impact

When an item rack is used for analysis, the patient information should be normally blank, however, if this defect occurs, incorrect patient information is displayed. Therefore, a possibility of a health hazard due to a misdiagnosis can't be denied. However, since patient information which should be normally blank is displayed and it overlaps with correct result which was remeasured after the occurrence of the error under the Condition (1), we believe that this defect can be detected and the avoidance is high. We haven't been informed of any diagnosis based on incorrect patient information or health hazard at this point.

4. Cause

It is considered to be a defect of the program.

5. Countermeasures

The program will be upgraded to prevent incorrect patient information from being linked even when only the main unit is shout down without shutting down the IPU.

6. Cautions to be paid before the program change

When shutting down, please shutdown both the Main Unit and the IPU in accordance with the Instruction Manual "4.6 Shutting down the instrument". As for 8.8.4 "Cleaning or replacing the sample filter", shutdown both the Main Unit and IPU as well. In this case, no dialog box is displayed and the box can't be checked, however, other operations can be performed without any problems.

END

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