March 13th 2019

URGENT FIELD SAFETY NOTICE

DxA 5000 Automation System

Attention Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the following issues for the DxA 5000 Automation System:

- Samples waiting on the DxA system
- Centrifuge error handling
- ECSD temperature control
- System stability

These are being addressed by an update to software and IFU which you will receive from your Field Service Engineer. You will be contacted by them to schedule your software update.

Samples waiting on the DxA system	Update to FSN-18064
ISSUE:	We have received and observed several instances in which, due to a software anomaly, samples remain waiting on the DxA system and are not transferred.
IMPACT:	Samples waiting on the system may be processed with increased turn-around times, and lead to a delay in reporting patient test results to the physician. In a worst case scenario where sample or test stability has expired due to samples waiting in buffer areas, a connected analyzer could generate erroneous but believable results.
ACTION:	Be aware of DxA 5000 sample turn-around-time timeout alerts, and when alerted check system for sample tubes waiting in the buffer area or input and output areas, and reload them onto the system. Throughout the day periodically check the system for sample tubes waiting in these areas, and reload them onto the system.
RESOLUTION:	A software update will be released to address the issue and installed by your Beckman Coulter Field Service Engineer.

Centrifuge error handling	IPN-19007
ISSUE:	We have received a report of the DxA 5000 centrifuge module adapter handler being bent during error recovery handling.
IMPACT:	If the adapter handler robot is bent by the drawer; the system may not be able to continue centrifuging samples and may require service intervention to replace the part.
ACTION:	Before performing error handling on the centrifuge module, ensure removal of the adapter if there is a centrifuge adapter present in the centrifuge adapter handler.
RESOLUTION:	Error recovery instructions for the centrifuge module in the IFU will be updated to reflect this information.

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ECSD temperature control	FSN-19008
ISSUE:	We have received reports that, depending on the laboratory ambient temperature and frequency of rack transfer, the online storage system for DxA 5000 has been observed to maintain samples at a temperature outside of the range claimed in performance specifications.
IMPACT:	The maximum permissible storage times for clinical patient test samples are influenced by the environmental conditions in which those samples are stored. A critical condition for the safe storage of samples is the temperature the sample is kept at. Across all sample and test types an increase in storage temperature may result in an increase to the degradation rate of those samples while they are being stored. If the device is operating outside of that range there is a possibility that the accuracy of test results on patient samples could be impacted.
ACTION:	The temperature specifications that can be maintained within the ECSD are 4-12 °C; please plan your storage protocol accordingly. Ensure that the operating environment of the DxA 5000 ECSD is kept between 16-27 °C.
RESOLUTION:	Changes will be made to the IFU, to state the correct performance specifications of the ECSD (4-12 °C; previously 4-8 °C), and to state the operating environment the ECSD/DxA 5000 must be kept at is between 16-27 °C (previously 16-32 °C).

System stability	IPN-19009
ISSUE:	We have received reports of software errors which required a system restart to be resolved.
IMPACT:	Since a full system restart involves removing all samples from the line this can have impact on the ability to process samples within the expected turn-around-time.
ACTION:	For error recovery, please follow the instructions given in the IFU, in particular the Section “Handling Sample Tubes after a System Crash ". To avoid delay in identifying STAT sample tubes after a system crash, we highly recommend that you define a mechanism of labeling the tubes for faster identification and handling.
RESOLUTION:	With the introduction of the next software release, the frequency of required restarts is expected to be reduced.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

If you are a centralized license holder, please provide the other affected laboratories of your organization or association with a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact Beckman Coulter via:

- Our website: http://www.beckmancoulter.com
- By phone: contact your local Beckman Coulter representative.

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We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Franck Cheillan
Director - Quality & Regulatory Affairs

Enclosure: Response Form

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