Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution onthis issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please informus about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah
Regulatory Affairs Specialist

Contact person of this notification	Chong Chuen Ling.....
Department	... Marketing.....
Telephone	...6012 982 6529.....
Fax	...603 7772 0551.....
E-mail	... cchong01@beckman.com .....

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
No 18, Jalan Tandang 51/205A,
Seksyen 51, 46050 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Tel : (603) 77728256
Fax : (603) 77720551
Website : www.beckmancoulter.com

March 29, 2023

URGENT FIELD SAFETY NOTICE

iQ200 Series, DxU 850m and 840m Iris Analyzers

REF	Operating System and Software Version
All iQ200 Series Analyzers	Windows 10, Software Version 8.1
All DxU 850m and 840m Iris Analyzers	Windows 10, Software Versions 8.5, 8.5.1 and 8.6

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Beckman Coulter has become aware of an intermittent issue in which the optional flag "Previous Sample Had Sperm" was enabled but not displayed so that a carryover event could have been investigated.
IMPACT:	If your laboratory is reporting Sperm, the following outcomes may occur intermittently: • Possibility of "Previous Sample Had Sperm" flag not being displayed leading to a possible false positive sperm result reported to physician. • Certain patient demographics (e.g. underage and vulnerable females) may undergo unnecessary evaluation and/or treatment.

ACTION:	Examine your specimen settings to determine if the optional "Sperm Present" and "Previous Sample Had Sperm" flags are enabled.
	• If disabled, no further action is needed by your laboratory.
	• If enabled, follow the actions below:
	  ○ If the presence of sperm is identified:
	  ▪ Review the previous specimen for the presence of sperm.
	  ▪ Follow recommendations under Previous Sample Had Sperm in the iQ200 Series Instructions For Use (IFU) 300-4320CE and 300-4321EE and DxU 850m and DxU 840m Iris IFU (C49320AB) in Chapter 6, Data Review, Flags, Previous Sample Had Sperm, Recommendations.

RESOLUTION:	Beckman Coulter is actively investigating the issue to prevent re-occurrence of the issue.

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 have forwarded any of the affected product(s) listed above to another laboratory, please provide them 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 our Customer Support Center or your local support representative;

- From our website: http://www.beckmancoulter.com
- By phone: call 800-526-7694 in the United States and Canada.
  - Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Medha Avisetti
Signer Name: Medha Avisetti
Signing Reason: I approve this document
Signing Time: 29-Mar-2023 | 2:27:47 PM PDT
5299CE6287024259B19FDD702D07C54E

Medha Avisetti
Vice President, QRA Hematology, UA, LS, CDSS & GQM

Enclosure: Response Form