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BD

Helping all people
live healthy lives

URGENT
Field Corrective Action

July 2015

Product Name	Version Number	BD MAX System Serial Number(s)
BD MAX System Software	4.44A	Insert customer specific serial numbers

Dear Enter Customer Name,

BD has determined that BD MAX System software version 4.44A contains a software anomaly that has the potential to affect some Open System Reagent (OSR) customers utilizing User Defined Protocol (UDP) assays. Customers utilizing **only** IVD assays are not affected.

This anomaly may cause the OSR customer system to incorrectly switch the columns of the truth table on the user's display. If the user tries to fix their display data, the display will appear correct however, the database may become incorrect, potentially resulting in incorrect results reporting.

Our records indicate that you were shipped the above-referenced serial number(s) or have been upgraded to this software version in the past three months.

BD is currently developing and validating an update to the software to correct this issue. We anticipate that the new software will be available by the end of August 2015.

Until the software can be updated on your instrument, please note the following OSR workflow instructions to ensure that the above-described situation does not occur. No action is required for IVD assay users. The steps below apply only to those customers who use Open System Reagent (OSR) utilizing User Defined Protocol (UDP) assays. Please follow the steps below to assess if your instrument or results may have been impacted.

- For each UDP test listed in the Test Editor, review the UDP report. Users may follow the instructions in Section 5.5.3.2 UDP Reporting of the BD MAX Systems User Manual to print a UDP report for all tests that contain result logic.
- If the result logic is correctly defined within the UDP report, this UDP is not affected. You may continue to use result logic for interpreting results of this UDP. The "Edit Logic" dialogue box should not be opened or used at this time.
- If the result logic is not correctly defined within the UDP report, then do not use the result logic for interpreting results. Results for this test should only be interpreted manually using PCR curves and Ct results. To help prevent inadvertent use, it is recommended to disable all results logic interpretation for the affected test(s).

Please complete the attached form, confirming your instrument serial number(s) so that we may acknowledge your receipt of this notification. It is not necessary to contact BD by telephone regarding this matter; a BD Service Representative will contact you to schedule an appointment for the software update when it becomes available.

If you require further assistance or clarification, please contact the BD Technical Services Department at 1-800-638-8663.

Please accept our apology for any inconvenience this situation may cause. BD is committed to providing you with the highest quality products and ensuring limited impact to your lab during this particular issue. Thank you for your continued support.

_____   _____
Traci Prouser   Gail Claiborne
Global Product Manager, BD MAX™ System   Regulatory Compliance

Fax or Email to: BD Regulatory Compliance
Fax #: 410-316-4258
Email: BDRC2@bd.com

PLEASE RETURN THIS FORM SO THAT WE MAY ACKNOWLEDGE YOUR RECEIPT OF THIS NOTIFICATION

Please do not send multiple forms.

Product Name	Catalog Number
BD MAX System	441916

Facility: _____

Please use full, current facility name. Do not use initials.

BD MAX System Serial Number(s) :	
Address	
Contact Person:	
Telephone:	
Fax:	
Email:	

Please indicate for our records if you are currently running IVD assays or if you are an Open System User running UDP Assays (or both).

IVD   Yes / No   (please circle one)

UDP Yes / No   (please circle one)

FOR BD USE ONLY		
BILL TO ACC'T NO. **9000000446**	ORDER REASON **517**	DELIVERY P.O. NO.
SHIP TO ACC'T NO.	JUSTIFICATION CODE	INVOICE P.O. NO.