30 Tuas Avenue 2
Singapore 639461
Registration No.
201114149N

bd.com

URGENT FIELD SAFETY NOTICE – BDDS-19-1617
BD Kiestra™ InoqulA™ / InoqulA+™

1 August 2019

Dear Customer

cc: Chairman Medical Board and relevant Head of Departments

Description of the problem and health hazard(s):
BD recently identified through a customer complaint investigation that an anomaly is present in InoqulATM / InoqulA+TM software version 20.3. This software anomaly has the potential to cause a mismatch between a specimen and plate. While it has not been ruled out that the anomaly can cause a mismatch in other instances, BD has observed that the mismatch can happen when following conditions occur together:

- The InoqulA hardware is not operating, such as during a power outage, and
- the pipette has already drawn a specimen waiting to be dispensed on a plate, and
- the user selects the Reset function from the System Menu.

Incorrect association of data has the potential to lead to a delay in test results and/or reporting of an incorrect test result. The impact to the patient could be a delay in treatment or a misdiagnosis leading to inappropriate treatment.

Our records indicate you have installed the Kiestra instrument and are using the InoqulATM / InoqulA+TM software version 20.3.

Catalog number	Serial number
447213	INO-000290

Please Take the Following Actions:

1. Do not utilize the Reset function from the System Menu of InoqulA™ software until further notice. Refer to the image on page 2.

2. In order to reboot the InoqulATM software, close the InoqulATM software application by selecting the "x" in the upper right corner. Refer to the image above. The InoqulATM software can then be restarted by double clicking the InoqulATM software's icon on the desktop.

3. Complete the attached Customer Response Form and return to the BD contact noted on the form so that BD may acknowledge your receipt of this notification.

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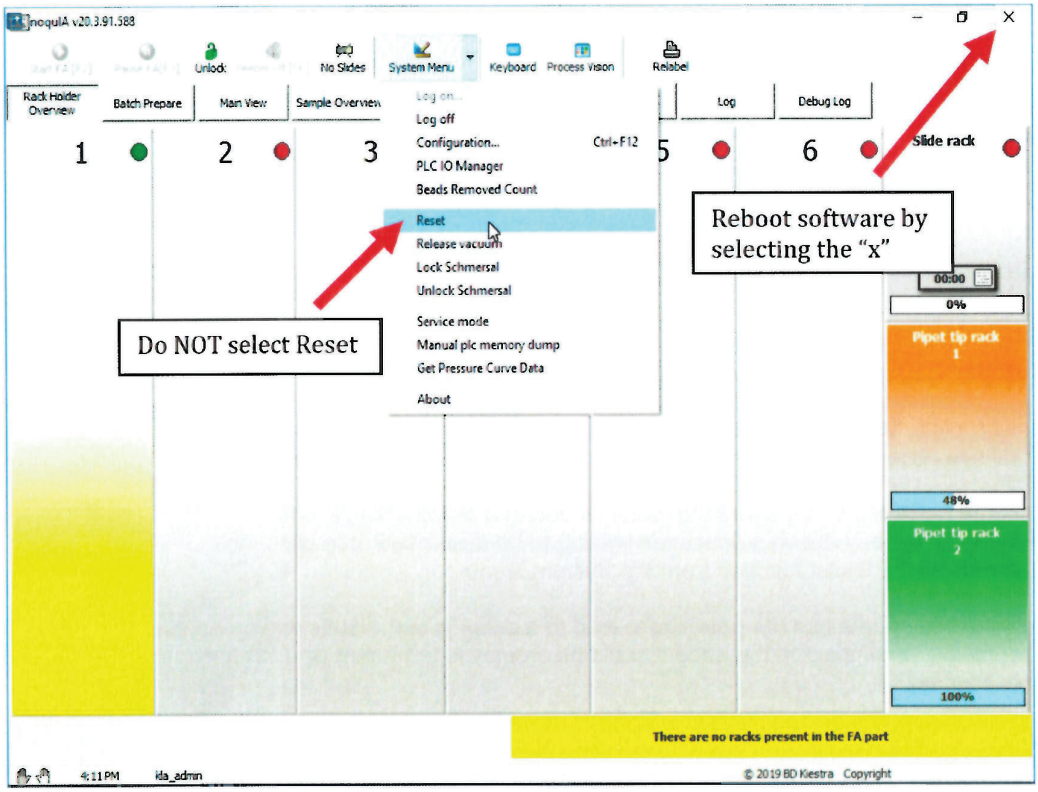

Actions Taken by BD:

1. BD is in the process of evaluating the log files of customers using the InoqulATM / InoqulA+TM software version 20.3 to determine if any users potentially experienced mismatch between a specimen and plate. BD will contact all customers using InoqulATM / InoqulA+TM software version 20.3 to provide the outcome of this evaluation.

2. A software update has been developed to correct this software anomaly and prevent future recurrence.

3. BD will contact you to schedule service to update your software.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours Sincerely,

[redacted] 01 Aug 2019

Phua Ai Tin
Quality & Compliance Manager
Greater Asia

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CUSTOMER RESPONSE FORM

BDDS-19-1617

BD Kiestra™ InoqulA™ / InoqulA+™

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to Kian Yean Tiu [redacted] / Alex Lim [redacted] by 30 August 2019.

Please tick as appropriate.

☐ I have read and understood the attached notice & will share this Urgent Field Safety Notice with all users within my facility.

Catalog number	Serial number
447213	INO-000290

Completed by:

Name: _____

Signature: _____

Date: _____

Facility: _____

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

Street Address: _____

Telephone No.: _____