

24 Jun 2021

Field Safety Notice

Reason: BOND ID Imager Issue

Impacted Products:

Product Name	Product Code	Serial Number Range
BOND-MAX	49.0051	M496593 to M496600, M496602 to M496608, M496610, M496612, M496615 to M496630, M496632
BOND-III	21.2201	3213008, 3213014 to 3213015, 3213018, 3213032 to 3213034, 3213036 to 3213038, 3213049, 3213052

Dear valued customer,

This is to notify you that the BOND ID Imager in your instrument provided by Leica Biosystems Melbourne has been observed to incorrectly read adjacent reagent racks.

Description of the problem:

The BOND ID imager reads the barcodes on the top of reagent containers that are loaded onto the BOND instrument with the BOND Reagent Tray. When a reagent tray is inserted into the instrument with empty slots (i.e. no containers), the imager can incorrectly scan barcodes of reagent containers present in the adjacent BOND Reagent Tray to the right. As a result of the incorrect detection, if a run is in progress, the issue may result in a run being abandoned and slides being unprocessed. Please note, there is no risk of incorrect reagent container detection nor use if a container is present in the slot being scanned by the 2D scanner.

The issue occurs if a tray is loaded to the left of another tray and happens to have empty slots adjacent to filled ones from the right-hand side tray. When this occurs, it can cause the instrument to identify reagent containers in an incorrect location. This causes the instrument to do a reagent substitution with a bulk reagent (BOND Wash or DI water), compromising those slides. If only some of the slides in a tray are impacted, the staining run will continue to complete the uncompromised slides. If all slides in a tray are impacted, the run will be abandoned after the bulk reagent substitution. In both instances, it is recommended to review the run events of the compromised slides to determine if the slides can be reprocessed or need to be replaced.

Advice on action to be taken by the user:

A permanent fix is currently being developed and will require a Field Service Engineer to implement on your instrument. In the interim, to continue using your BOND instrument we recommend employing one of two methods to reduce the risk of this failure mode occurring.

1. Load detection kit on the left and load reagent trays left to right.

The issue occurs if a tray is loaded to the right of a tray with empty adjacent slots. Loading trays left to right resolves this. We would recommend loading your detection kit(s) first on the left and use the right-hand side trays for hot swapping reagents during the days processing. After loading any reagent rack, confirm the graphical user interface of reagent distribution matches the physical reagent layout.

2. Fill all BOND reagent trays with containers

Fill all BOND reagent tray slot with containers. These containers do not need to be used for staining (e.g. use closed lid containers), they merely provide a physical barrier to stop the BOND imager from being able to scan adjacent containers. This method does not require loading from left to right but does require all slots in reagent trays in use to include BOND reagent containers.

Transmission of this Field Notice:

Kindly pass this notice primarily to the end users where the product has been sold and to all those within your organization who need to be aware of this issue.

If your facility would like assistance with implementing this process, please contact your local Leica representative to allow us to assist you.

Your local Leica Biosystems representative will arrange with you a suitable time for a Field Service Engineer to attend your facility to implement the permanent fix as soon as it becomes available.

Please confirm receipt of this notice as soon as possible by signing and dating the attached Field Safety Notice Acknowledgement Form and sending it to Leica Biosystems.

Please scan the completed document and return it using the email address below:

RA.LBSMEL@LEICABIOSYSTEMS.COM

Your cooperation in this matter is greatly appreciated. We sincerely apologise for any inconvenience this may have caused.

Regards,



Contact reference person:

Adrienne Hardisty
Leica Biosystems Melbourne Pty Ltd
495 Blackburn Road
Mount Waverley
Victoria 3149
Australia
Telephone: +61 3 9211 7535

Reference: 202106-01

ACKNOWLEDGEMENT FORM

BOND ID Imager

Instrument Serial Number(s): _____

I hereby acknowledge receipt of the **BOND ID Imager** notification.

Contact Person (Please Print)

Signature

Date

Facility Name (Please Print)

Please email this form to the following within 5 days of receipt:

RA.LBSMEL@LEICABIOSYSTEMS.COM