

BOND-PRIME Customer Release Notes



Dear BOND-PRIME Customer,

This document provides you with information about the BOND-PRIME IHC and ISH staining system. It outlines known issues and potential workarounds.

By bringing these issues, and their workarounds, to your attention, we hope to ease any inconvenience that they may cause.

The information is for awareness only and does not replace any existing guidance in the BOND-PRIME Product User Manual or BOND-PRIME Quick Tips.

Leica Biosystems practises continuous improvement, and we will update this document as issues are resolved.

We look forward to receiving your feedback on BOND-PRIME, so that we can continue to provide you with the highest quality IHC and ISH staining device.

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Known Issues and Workarounds

Leica Biosystems has taken every effort to ensure a high-quality system that meets your needs. This software release includes unresolved issues. These issues have been reviewed and do not impact device intended use, device safety or effectiveness of the system.

The list of unresolved issues is outlined below, along with any mitigations or workarounds to assist in proper operation of the device.

Applicable Software Versions

The Software versions can be viewed on the BOND Clinical Controller. Click the Leica Biosystems logo at the top right of the screen to view the About BOND dialog, which lists system information.

BOND Clinical Controller - Software version	7.3 (or above)
BOND-PRIME Processing Module - Application Software version	1.7.0

Note: Please be aware that this document will only be revised for future software versions if there are changes to the known issues or workaround processes described within as a result of the software update. If there are no changes to these issues or processes, this document will not be updated. If you need to confirm that you have the latest software customer release notes, please contact your local sales or service representative for assistance.

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Affected Area	Explanation	Workaround
<p>Locked Bulk Reagent Containers: refill with BOND-PRIME Wash Solution Concentrate</p> <p>(Issue ID: TAIPROG-3080)</p>	<p>When BOND-PRIME Wash Solution Concentrate is refilled, the touchscreen popup window abbreviated title is “Refill *BWash”.</p> <p>The popup window abbreviated title should be “Refill *BWash Concentrate”, as BOND-PRIME performs onboard BOND-PRIME Wash mixing, unlike other BOND processing modules.</p>	<p>None.</p>
<p>Cancel slide: reporting</p> <p>(Issue ID: TAIPROG-3207)</p>	<p>On the Run Events Report for a cancelled slide, the Event 29164 “Slide processing has been cancelled” can appear before the Event 27004 “Reagent dispensed with Wash Robot”.</p> <p>The ordering of the Events is incorrect, but this does not indicate an issue has occurred as both events occur simultaneously.</p>	<p>This issue occurs as both events have the same time stamp – but an incorrect sort order in the report.</p> <ul style="list-style-type: none"> Ignore the ordering of the Events on the Run Events Report, for a cancelled slide’s last dispense. The slide will finish its current step before cancelling the slide and taking it to the Unload Drawer.
<p>Reagents screen: unregistered reagents</p> <p>(Issue IDs: TAIPROG-3285, TAIPROG-3398)</p>	<p>If a Reagent Tray contains one or more reagents that are not registered on the BOND Controller, then the spinning icons may remain displayed on the BOND-PRIME Reagents screen, even after the Reagent Trays have been scanned, rather than resolving to display the Reagents.</p> <p>There is no message raised to the Action Queue to advise the cause for this issue is that one or more reagents is not registered.</p>	<ul style="list-style-type: none"> Check that the Reagent Tray is unlocked Remove the Reagent Tray Register the reagents on the BOND Controller Re-load the Reagent Tray onto the processing module.

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<p>Use the BOND-PRIME Cleaning Kit: Action Queue message</p> <p>(Issue ID: TAIPROG-3441)</p>	<p>When the first ARC Module's usage count reaches 23, an Action Queue message states that "Some ARC Modules are disabled until cleaning is completed. (29129)"</p> <p>However, the ARC Module on the Status screen does not display as disabled until the ARC Module becomes unoccupied.</p>	<p>The first ARC Module that reaches a usage count of 23 will display as disabled on the Status screen only <u>after</u> the slide has been transferred from that ARC Module to the Unload Drawer.</p>
<p>Maintenance: ARC Module Lid position</p> <p>(Issue ID: TAIPROG-3492)</p>	<p>If an ARC Module lid is left in a partially open position during maintenance, then stopping maintenance may be unsuccessful.</p> <p>The processing module expects the lid of the ARC Module to be in the fully open position when stopping maintenance otherwise it may interpret a slide as being present in the ARC Module.</p> <p>An Action Queue message and pop-up Window will be displayed and will advise you to remove the detected slide from the ARC Module.</p>	<p>Always ensure all ARC Modules lids are fully open before stopping maintenance.</p> <p>If this issue occurs:</p> <ul style="list-style-type: none"> • Tap 'ok' on the "Unable to stop maintenance" window • Lift the Hood • Manually position the ARC Module lids to a fully open position • Lower the Hood • Tap the 'Stop maintenance' button.
<p>Detailed case and slide information window: case completion time</p> <p>(Issue ID: TAIPROG-3512)</p>	<p>The case completion time displayed at the top of the Detailed case and slide information window can display an incorrect time when the Unload Drawer is full and slides in that case have completed processing on ARC Modules.</p> <p>Slides that have completed processing on ARC Modules have their completion time cleared until they can be transferred to the Unload Drawer.</p>	<p>The case complete time, at the top of the Detailed case and slide information window, will update to the correct time once the Unload Drawer is emptied and slides on ARC Modules start transferring to the Unload Drawer.</p>

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<p>Dual Reagent Tray: BOND-PRIME Polymer DAB Detection System</p> <p>(Issue ID: TAIPROG-3524)</p>	<p>If the barcode (UPI) on the sixth Reagent Container in the BOND-PRIME Polymer DAB Detection System fails to be identified because the lid is closed, the label is damaged or the camera cannot decode the barcode, then the 'Reagent system incomplete' message appears in the Action Queue.</p> <p>Removing the kit, fixing the barcode, and then re-inserting the Reagent Tray may result in a different message, 'Reagent already in use', appearing in the Action Queue.</p>	<p>Remove and then re-insert the Dual Reagent Tray into the same lanes in the Reagent Platform that they were originally loaded.</p> <p>If the 'Reagent already in use' message keeps appearing for that Detection System, then restart the processing module when convenient to allow the Detection System to be used on this or another processing module.</p>
<p>Slide rejected: no message</p> <p>(Issue ID: TAIPROG-3538)</p>	<p>When an ARC Module's usage count is 22 (one usage before its maximum limit of 23) then it will not be used to process an ISH slide, but the ARC Module still displays on the Status screen as available. (An ISH slide counts as two usages of an ARC Module.)</p> <p>When there are no remaining ARC Modules with a usage count less than 22, then ISH slides in the Preload Drawer will display as evaluating for some time before finally being rejected without any message displayed.</p> <p>This issue occurs when cleaning is overdue.</p>	<ul style="list-style-type: none"> • Remove the ISH slides from the Preload Drawer. • IHC slides (single stain) can still be processed if some ARC Modules are displaying as available. • Use the BOND-PRIME Cleaning Kit. • The ISH slides can be loaded into the Preload Drawer once cleaning has been scheduled. • Refer to the BOND- PRIME User Manual 'Use the BOND-PRIME ARC Refresh Kit' for the slide type and equivalent slide count.
<p>Slide flagging: unwaxed slide message</p> <p>(Issue ID: TAIPROG-3550)</p>	<p>When the processing module is unable to scan slides in the Preload Drawer within the "Unwaxed slides" start limit, the system assumes that all slides are Unwaxed, and raises Event 29025 to the Action Queue for all slides.</p> <p>The slides are not rejected and will be processed in the normal manner.</p> <p>The 29025 message in the Action Queue is only applicable to unwaxed slides and can be ignored for waxed slides.</p>	<ul style="list-style-type: none"> • Ignore Event 29025 when it is raised to the Action Queue for waxed slides. Event 29025 will not appear on the Run Events Report for waxed slides, only for unwaxed slides. • If the Event is raised for Unwaxed slides, consider whether to unload the slide from the Preload Drawer and load it on another processing module with more capacity. • If you choose to leave the unwaxed slides in the Preload Drawer, they will be processed.

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<p>Cancel slide: slide unload (Issue ID: TAIPROG-3551)</p>	<p>If a cancelled slide is retrieved from the Unload Drawer before it is hydrated, then no further slides (completed or cancelled) will be transferred to the Unload Drawer.</p> <p>The slides must be manually removed after the processing module has been powered down.</p> <p>There is no message raised to the Action Queue to advise of this issue, but all slides remain on ARC Modules.</p>	<p>Always wait for all cancelled slides to be transferred to the Unload Drawer and complete hydration before unloading. Hydration can take a minute to occur after the slide has been placed in the Unload Drawer.</p> <p>If this issue does occur, then wait for all slides to complete processing on ARC Modules, then follow the instructions to power down the processing module and retrieve slides as per the BOND-PRIME User Manual:</p> <ul style="list-style-type: none"> • “Manually retrieve slides from Preload and Unload Drawers”; and • “Manually retrieve slides from ARC Modules”.
<p>Detailed case and slide information window: protocol display order (Issue ID: TAIPROG-3557)</p>	<p>In the Detailed case and slide information window, the protocols for each slide are displayed. In some instances, the order of the protocols may be incorrect.</p> <p>This is a display issue only and does not impact the correct processing of the slide.</p>	<p>If the order of protocols on the Detailed case and slide information window is in the incorrect order, then ignore the display.</p> <p>The protocols will be executed in the correct order when the slide is being processed. (Refer to the Run Details report on the BOND Controller.)</p>

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<p>Cancel slide: slide unload (Issue ID: TAIPROG-3582)</p>	<p>If an RNA ISH slide is cancelled during:</p> <ul style="list-style-type: none"> • RNA ISH Probe Application, or • RNA ISH Hybridization, or • RNA ISH Probe Removal, <p>The slide will not transfer to the Unload Drawer and will remain in the ARC Module.</p> <p>There is no message raised to indicate that this cancelled slide will remain in the ARC Module.</p> <p>Cancelled slides are displayed as red coloured on the Status screen and Unload screens.</p>	<p>Refer to the Run Events report to view protocol progress, before cancelling an RNA ISH slide.</p> <p>RNA ISH slide/s can be cancelled:</p> <ul style="list-style-type: none"> • before the RNA Probe has been dispensed, or • after the dispense of Peroxide Block. <p>If a cancelled RNA ISH slide is not moved to the Unload Drawer, wait for all other slides to complete processing and transfer to the Unload Drawer. Follow the instructions to power down the processing module and retrieve cancelled slides remaining in ARC Modules, as per the BOND-PRIME User Manual:</p> <ul style="list-style-type: none"> • “Manually retrieve slides from Preload and Unload Drawers”; and • “Manually retrieve slides from ARC Modules”.
<p>Empty the Waste Containers: DI Water and waste transfer (Issue ID: TAIPROG-3608)</p>	<p>If you repeatedly ignore Action Queue messages for DI Water almost empty or Waste Container full or leave Containers off the Processing Module for an extended period while processing slides, it is possible for the Processing Module to enter a state where intervention from a field service engineer is required before additional slides can be accepted for processing.</p> <p>In this state, refilling the DI Water Container and emptying Waste Containers will not fix the issue.</p>	<ul style="list-style-type: none"> • Always empty the Bulk Waste Container and Hazardous Waste Container as soon as the Action Queue messages with Warning (red icon) appear. • Always fill the DI Water Container as soon as the Action Queue message with Caution (amber icon) appears. • When re-inserting the DI Water and Waste Containers, listen for a click sound to confirm the container is locked in place. Make sure the container is fully inserted. • When processing slides on the BOND-PRIME, ensure that all Bulk Reagent Containers, and Waste containers are present. • If this state does occur, contact customer support.

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<p>Slide Scheduling and Instrument Constraints</p> <p>(Issue ID: TAIPROG-4097)</p>	<p>Slides are scheduled on the instrument based on several factors, including the type of staining and the status of the instrument's components.</p> <p>When slides are loaded into the Preload drawer, processing is planned according to the received instructions. ISH (In Situ Hybridization) and IHC (Immunohistochemistry) stains are treated differently—ISH typically requires more time and consumes more of the ARC Module usage capacity than IHC.</p> <p>In an optimal scenario Instrument can process up to 24 IHC slides but processing 24 ISH slides is not feasible unless each ARC Module has at least two remaining uses.</p> <p>When both ISH and IHC slides are present, careful allocation of ARC Modules is essential. If there have been prior issues—such as cleaning failures or unusually long IHC processing times—this can lead to scheduling conflict and ultimately cause the instrument to crash.</p>	<ul style="list-style-type: none"> • Remove the IHC slides from the Preload Drawer and close it. • Wait until all ISH slides are accepted and moved to ARC Modules. • IHC slides (single stain) can still be processed if some ARC Modules are displaying as available. • Place the IHC slides in the Preload Drawer and close it. • Alternatively, user can remove all slides from the Preload drawer, perform comprehensive cleaning of the Instrument and then place the slides in the Preload Drawer. • In the event of an uncontrolled Instrument failure, User will need to re-start the Instrument.
<p>BOND-PRIME not reconnecting with BOND Controller after reboot</p> <p>(Issue ID: TAIPROG-4105)</p>	<p>The instrument software fails to establish a connection with the BOND Controller due to communication failures after the Controller is rebooted. These communication failures are not expected during the normal operations.</p>	<p>Reboot the BOND-PRIME instrument whenever BOND Controller is rebooted.</p>

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<p>Slide State Colour Code Discrepancy</p> <p>(Issue ID: TAIPROG-5344)</p>	<p>Due to low bulk reagent volume, some slides were initially rejected and left in the Preload Drawer. However, when the in-progress slides complete the assigned protocol, Instrument recalculates the bulk reagent volumes and processes the previously rejected slides.</p> <p>Despite successful processing, slide icons remained amber instead of turning blue (in progress) or green (completed).</p>	<p>Remove rejected slides from the Preload Drawer until the reason for rejection has been addressed.</p> <p>If slides do run, Users should consult the Run Events reports to ensure no flaggable events occurred.</p> <p>Note that the slides are processed correctly and without any flagging or intervention from the user.</p>
<p>Action Queue – repeated warnings</p> <p>(Issue ID: TAIPROG-6010)</p>	<p>When a rejected slide is left in the Preload Drawer, it will be periodically re-evaluated. If the reason for the rejection isn't addressed it will be repeatedly rejected creating duplicate Action Queue items and audible alerts that create confusion.</p>	<p>Remove rejected slides from the Preload Drawer until the reason for rejection has been addressed.</p>
<p>Action Queue - insufficient Bulk Reagent message</p> <p>(Issue ID: TAIPROG-6012)</p>	<p>When loading a slide (or slides), the Action Queue can display a message indicating insufficient bulk reagent and recommend a bulk reagent refill even when the bulk container is full. For example: Insufficient ER2 Refill the Bulk ER2 Container (29042). This can occur when all of the volume of a Bulk Container has been allocated to running or scheduled slides. A more correct message would be: Total ER2 volume allocated to scheduled slides.</p>	<p>Wait for running slides to complete or top up the Bulk Container as the reagent is used and the volume drops.</p>