

FIELD SAFETY NOTIFICATION

Product Name: BOND PRIME

Date: 15th January 2025

Attention: Pathology Department / Channel Partner

Details on affected devices:

This Safety Notice is applicable to the BOND-PRIME instrument/s supplied and installed at your site by Leica Biosystems from the list in the below table.

Instrument Model Number	Impacted Instrument Serial Numbers		
91.0021	P9723020075	P9724030196	P9724060264
	P9723020079	P9724030205	P9724070279
	P9723030080	P9724030207	P9724080283
	P9723030085	P9724040211	P9724080299
	P9723080123	P9724040213	P9724090325
	P9723120169	P9724040214	P9724100329
	P9724110342	P9724040216	
	P9724020184	P9724040218	
	P9724020186	P9724040222	
	P9724020188	P9724050242	
	P9724020189	P9724050246	
	P9724030193	P9724060251	

Description of the problem:

Leica Biosystems has become aware that customers using BOND-PRIME instruments installed at 250mASL (820 ftASL) or more may observe sub-optimal chromogenic staining intermittently. Investigation has revealed that with the increase in altitude, the boiling point of some reagents is reduced, which can cause the reagent to evacuate the staining chamber more rapidly than expected, causing sub-optimal chromogenic staining of the tissue samples. You are receiving this

safety notice because your laboratory's location is such that it may be potentially impacted by the sub-optimal chromogenic staining issue.

ACTIONS REQUIRED

1. Follow the instructions provided in Appendix A

As your laboratory is situated at 250m ASL (820 ftASL) or more, please refer to the instructions provided in Appendix A of this safety notice. Your local Leica field representative can provide further guidance on this.

2. Confirm Receipt of Field Safety Notice

Please confirm receipt of this safety notice by signing and dating the attached Field Safety Notification Acknowledgement Form (below) by email to the following email address: lbsmel.qa@leicabiosystems.com

Please contact your local Leica representative immediately if you have any questions or concerns.

Transmission of this Safety Notice:

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

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

Yours sincerely



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FIELD SAFETY NOTIFICATION ACKNOWLEDGEMENT FORM

BOND PRIME

The following BOND-PRIME serial numbers are affected at my site:

Model Number	Affected Serial Number
91.0021	

I hereby acknowledge receipt of the Leica Biosystems Field Safety Notification on behalf of:

Facility Name (Please Print)

Facility Address (Please Print)

Contact Person (Please Print)

First Contacted on _____
Date

by _____
(Please print name of the Leica Representative)

Signature

Date

Please scan and email the completed form to:

Email: lbsmel.qa@leicabiosystems.com

APPENDIX A: CUSTOMER NOTICE

Due to the properties of reagents used in IHC, allowances may be required for the environmental conditions found at each site. In particular, the boiling point of Epitope Retrieval solutions varies with air pressure as experienced at different altitudes. This means that sites at or above 250 mASL (820 ftASL) may experience a lower Epitope Retrieval solution boiling point which could lead to an area of suboptimal chromogenic staining.

Each site at the altitude ranges listed below should therefore consider their altitude when setting Epitope Retrieval (ER) temperatures as part of optimization and validation.

The table below provides suggested temperature settings for different altitude ranges for Heat Induced Epitope Retrieval (HIER) protocols. If your laboratory consistently achieves high quality stains using alternate temperature settings to those proposed in [Table 1-1](#), there is no need to adopt the suggested temperatures.



BOND-PRIME is not suitable for altitudes above 2250 meters Above Sea Level (mASL) (7381 feet Above Sea Level (ftASL)).

Table 1-1: Recommended HIER protocol temperature by altitude range

Altitude range (mASL)	Altitude range (ftASL)	Temperature in software (°C)
0 – 249	0 – 819	104 (default)
250 – 449	820 – 1475	102
450 – 799	1476 – 2624	101
800 – 1149	2625 – 3772	100
1150 – 1499	3773 – 4920	99
1500 – 1849	4921 – 6069	98
1850 – 2250	6070 – 7381	96

Contact your Leica Biosystems representative for a step-by-step guide on modifying the HIER temperature for BOND-PRIME. You can also refer to Chapter 7 of the *BOND 7 User Manual* for guidance on how to edit protocols.

Note that these are suggested temperatures only and each laboratory is responsible for validating assays in their environment as staining can be impacted by many factors. If you experience staining issues, contact your Leica Biosystems representative before making the changes to the predefined protocols.

The maximum altitude figure in this communication replaces the figure in the *BOND-PRIME User Manual* (91.7500.501). The recommended temperature settings are in addition to the instructions in the *BOND 7 User Manual* (49.7556.501).

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