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## **URGENT MEDICAL DEVICE FIELD ACTION**

**Product Name:** BOND Slide Labeler Zebra Printer Power Supply Unit (PSU) for use with BOND-III and BOND-MAX instruments.

**Reason:** Potential of Zebra Printer PSU overheating or causing a fire hazard.

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Date: 03 September 2018

Attention: Pathology Department / Dealer

### **Details on affected devices:**

This Recall Notice is applicable to the Zebra PSU for the Zebra printer models detailed below, which were supplied by Leica Biosystems as part of the BOND Slide Labeler for use with BOND-III and BOND-MAX instruments:

<b>Printer Model Number</b>	<b>Affected PSU Part Number</b>
Zebra TLP3842	808113-001 or P1028888-001
Zebra GX430t	808101-001

The recall includes PSUs manufactured by the FSP Group between October 1 2006 and December 31 2012. In order to ensure complete coverage, the printer models detailed above were supplied by Leica Biosystems, both within the recall period timeframe, and outside the recall timeframe.

### **Description of the problem:**

Leica Biosystems has become aware that a manufacturer (Zebra) of a series of printers that have been utilized by Leica Biosystems as part of the BOND system, referred to by Leica Biosystems as the BOND Slide Labeler, has communicated a recall for the Zebra Printer Power Supply Unit (PSU). The Zebra Printer PSUs for the affected models of Zebra printers detailed above, which serve as the external power source for these printers, have been identified as potentially containing an improperly mixed phosphorus compound that is used in the flame retardant resin in the DC power supply connectors. This deficiency in the phosphorus based connector resin, when combined with moisture and humidity over time, can potentially lead to overheating or a fire hazard.

Adrienne Hardisty · RA/QA Manager · Leica Biosystems Melbourne

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## ACTIONS REQUIRED

### 1. Collect Printer Serial Number(s):

Locate and record the serial number of all affected printers, which can be found on the label adhered to the bottom or back of the printer.

### 2. Collect Power Supply Date(s):

For each of the printers identified above, disconnect the PSU from the printer and examine the "brick" to locate the date code, which is marked with "D/C". Please ensure that all spare power supplies not currently attached to printers are also checked.

### 3. Check Power Supply Date Code(s):

If the date code is in the range 0639XX through 1253XX (YYWWXX, where YY=year and WW=week), the PSU has been included in the voluntary PSU recall.

Immediately disconnect the PSU and please visit the following website: [www.zebra.com/power-supply-recall](http://www.zebra.com/power-supply-recall) for information on how to initiate the PSU replacement process. The Zebra Printer PSU replacement process is being managed by Zebra and not Leica Biosystems.

If the date code is NOT within this date range, the PSU is not included in the voluntary PSU recall, and you can continue to use the PSU with the appropriate Zebra printer.

NOTE: PSUs manufactured by Hitek are NOT affected by the recall.

### 4. Confirm Receipt of Recall Notice

Please confirm receipt of this notice by signing and dating the attached Recall Notice Acknowledgement Form; and return by emailing a scanned copy to the following email address: [lbsmel.qa@leicabiosystems.com](mailto:lbsmel.qa@leicabiosystems.com)

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

#### **Transmission of this Recall Notice:**

Kindly pass this notice primarily to the end users where the product 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,

  
Adrienne Hardisty  
Regulatory Affairs and Quality Assurance Manager  
Leica Biosystems Melbourne  
Tel: +613 9211 7400  
Email: 

## FIELD ACTION NOTIFICATION ACKNOWLEDGEMENT FORM

**BOND Slide Labeler Zebra Printer Power Supply Unit (PSU) for use with  
BOND-III and BOND-MAX instruments.**

The following Zebra Printer model numbers and associated Zebra Printer PSUs are affected:

Printer Model Number	Affected PSU Part Number
Zebra TLP3842	808113-001 or P1028888-001
Zebra GX430t	808101-001

*I hereby acknowledge receipt of the Leica Biosystems Field Action Notification*

\_\_\_\_\_  
Contact Person (Please Print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Facility Name (Please Print)

***Please scan and email the completed form to:***

***Email: [lbsmel.qa@leicabiosystems.com](mailto:lbsmel.qa@leicabiosystems.com)***

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