

Urgent Field Safety Notice

SBN-SIS-2018-002

SIS / Laboratory Integration
Version 1
07-Dec-2018

Defective Power Supply Unit for external Barcode Printer in combination with cobas 8100

Product Name	Power Supply Unit for external Barcode Printer in combination with cobas 8100
Product Description	Power Supply Unit for external Barcode Printer
GMMI / Part No	07123841001 / 07123850001
Device Identifier	GX430t (external Barcode Printer)
Production Identifier (SN GX430t /cobas 8100)	32J132200293 / 1301-01, 32J124100473 / 1302-02, 32J132701073 / 1302-07, 32J132701081 / 1302-03, 32J132701066 / 1302-04, 32J132701060 / 1302-05, 32J132701079 / 1302-06
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Hitachi High Technology has been informed by the manufacturer, Zebra, about a potential safety issue with the Power Supply Unit of the barcode printer model GX430t, which is located outside of the cobas 8100 (accessory). The issue may lead to an excessive increase in temperature which could potentially lead to a fire. The manufacturer, Zebra, has recalled certain models of Power Supplies.

Roche Diagnostics became aware that 7 defective units were identified and associated with the cobas 8100. Therefore, Roche Diagnostics is informing about this issue in a sub-recall.

Actions taken by Roche Diagnostics

Defective Power Supply Units will be exchanged within the next 4 weeks following this message by the Roche Diagnostics Field Service Engineers.

Actions to be taken by the customer/user

Until the replacement part is implemented, the Field Service Engineer/Representative or customer has to cut the cable (where allowed by law) and discard the unit properly (see figure below).

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The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com