

# **RANDOX**

## **Urgent Field Safety Notice**

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Tel: +44 (0) 28 9445 1070

**Date Issued:** 10 June 2019

**Complaint Reference:** REC 393

**Action Type:** Awareness Notification

### **Detail on Affected Devices:**

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Rx Daytona Plus analyser	RX4040	██████████	All	N/A	N/A
	RX4041	██████████	All	N/A	N/A
RX imola analyser	RX4900	██████████	Serial No. ██████████	N/A	N/A

### **Reason for Action:**

Randox Laboratories would like to inform all users of an isolated incident associated with the RCU lid sensor. We have been informed of a malfunction with the sensor which has resulted in an increase of temperature leading to melting of internal wires and scorch damage to the internal structure of the instrument. Please be aware of any signs of abnormal smell and or damage to the lid and or magnetic sensor. If suspected signs of deterioration or damage are noted , please contact [technical.services@randox.com](mailto:technical.services@randox.com) immediately for further advise.

### **Risk to Health:**

If the fault occurs unnoticed there is a risk of scorch or electrical damage. Please note the likelihood of this occurring is remote.

### **Action to be taken:**

If there is any sign of damage to the RCU lid or lid sensor

- Switch of main analyser main power supply as soon as possible
- Contact technical support immediately.
- Discuss the contents of this notice with your Medical Director.
- Display this notice in a prominent location near the instrument.
- Complete and return the response form 12187-QA to [technical.services@randox.com](mailto:technical.services@randox.com) within five working days.

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**Transmission of Field Safety Notice:** Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Randox Technical Services.

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

A black rectangular box redacting the signature of the undersigned.