

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
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 | 05055273207774 | All | N/A | N/A |
| | RX4041 | 05055273207781 | All | N/A | N/A |
| RX imola analyser | RX4900 | 05055273205893 | Serial No. 7201-0724 and above | 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 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 within five working days.

RANDOX
Urgent Field Safety Notice

Radox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@radox.com
Tel: +44 (0) 28 9445 1070

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 Radox Technical Services.

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


