RANDOX

Urgent Field Safety Notice

Software Update
RX Imola RX4900
GTIN: 05055273206104

Date: 06-Apr-18

Complaint Reference: 328 **Action Type:** Device Modification

Detail on Affected Devices: RX Imola (RX4900) GTIN: 05055273206104

Reason for Recall:

The RX Imola Software Update Versions are now available 2550328123(ENU) English, 2550444123(DEU) German, 2550445123(FRA) French, 2550446123(ITA) Italian, 2550447123(ESN) Spanish.

Changes included:

1. RX imola software is now compatible with Windows 10™ Operating System.
• Windows 10 is a registered trademark of Microsoft Corporation.
2. Changed some terminologies for Spanish translation (2550447123)
3. Corrected an issue where ISE counter alarms were generated even when the analyser was not installed with ISE unit.
4. Improved UDP communication processing to correct an issue where the software was occasionally and abnormally terminated.
5. Corrected an issue where the popup for round start occasionally stayed on and made operation of software, unavailable.
6. Corrected an issue where the software was abnormally terminated when importing more than 100 parameters at the same time.

Risk to Health:

Abnormal termination of the software will delay reporting of results and require repeat sample analysis. There is no impact on reported patient results for any of the changes implemented and therefore no requirement to review previously reported results.

Action to be taken:

- Discuss the contents of this notice with your Medical Director.
- Implement RX Imola Software Update as described in attached FSU (RXTB-0089)
- Complete and return the vigilance response section of this form to technical.services@randox.com within five working days.)

Form No. 6307-TS
REVISION (8)
27th September 2016

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.

Contact Reference:

Randox Technical Services
Randox Laboratories Ltd,
55 Diamond Road,
Crumlin,
United Kingdom,
BT29 4QY
Email: technical.services@randox.com
Tel: +44 (0) 28 9445 1070
Fax: +44 (0) 28 9445 2912

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

RANDOX

Urgent Field Safety Notice

Software Update
RX Imola RX4900
GTIN: 05055273206104

Vigilance Response Form (Response Plan must be completed by the importer of the device)

Importer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Area of Distribution

(To be completed by Distributors and Randox Offices)

Consignee	Country	Quantity Received	Analyser Serial Number	Replacements Required

I have read and understood the Urgent Field Safety Notice. The actions to be taken are completed.

Completed By				Date	
Contact	Tel		Email		

Form No. 6307-TS
REVISION (8)
27th September 2016