

# RANDOX

## Urgent Field Safety Notice

**Date:** 12 October 2018

**Complaint Reference:** REC 344

**Action Type:** Device Modification

### Detail on Affected Devices:

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

Device	Catalogue Number	GTIN
RX Monaco	RX5000	05055273207750

### Reason for Recall:

The RX Monaco software update version UI 3.017.001 is now available to download from the designated Radox FTP site.

### Changes included:

1. Correction: Improved communication for USB convert com port cable between the analyzer and computer (pc). *Only applicable to customers NOT using pcs supplied by Radox Laboratories Ltd.*
2. Upgrade: Now compatible with Windows Pro10 64 bit.
3. Upgrade: Allows the scanning of the sample barcode.
4. Upgrade: Reagent Inventory Feature. *When the user selects "Reagent continue" function, the analyser will carry out a reaction remain volume scan automatically. Analyser will scan and display the volume of the added reagent.*
5. Upgrade: Patient Information Interface can be edited.
6. Upgrade: A QC profile can be added in QC register page.
7. Upgrade: Calibration validity feature added to the calibration register interface.
8. Upgrade: Standby Time Count Down Function. *The analyser will display the remaining time to complete current round.*
9. Upgrade: Optimisation of the QC test for the log3p/log4p calibration method.

### Risk to Health:

For analysers systems not using the pc supplied by Radox Laboratories instability in communication between the analyser and the pc may result in termination of the software. 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

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### Action to be taken:

- Discuss the contents of this notice with your Medical Director.
- Read the FSU and Technical Bulletin provided
- Implement software changes and update the parameters as supplied
- Complete and return the vigilance response section of this form to [technical.services@randox.com](mailto:technical.services@randox.com) within five working days.)

**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](mailto: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**

  
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## Urgent Field Safety Notice

### Software Update

**RX Monaco RX5000**

**GTIN: 05055273207750**

### 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	

