RANDOX

# 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:** 12 November 2018

**Complaint Reference:** REC340

**Action Type:** Device Modification

**Detail on Affected Devices:** Evidence Investigator
Our records indicate that your facility may have received the following product

| Device Name | Catalogue Number | GTIN | Batch / Lot number | Expiry Date | Manufacturing Date |
|---|---|---|---|---|---|
| Evidence Investigator | EV3602 (EV3602R, EV4187) | 05055273209952 | n/a* | n/a | n/a |

*n/a not applicable

**Reason for Recall:**

Evidence Investigator software version 2.1.1 is now available. This includes a number of new features as detailed in the Software Release Notes in the accompanying email.
The software has also been modified to allow for enhanced detection of reference and correction DTRs.

**Risk to Health:**

Failure to detect reference and correction DTRs causes no test result to be reported. This requires a re-run of the test sample. A delay in reporting results could lead to a delay in patient treatment of up to 2 to 24 hours depending on the test array. The test menu for the Evidence Investigator does not include time critical diagnostic tests therefore the risk to health is negligible.

**Action to be taken:**

- Review the software release notes provided for further information.
- Please complete the mandatory software upgrade. Software update files can be accessed via the FTP site, guidance notes can be found in the accompanying email. The files should be saved onto a blank USB device.
- Discuss the contents of this notice with your Medical Director.



Form No. 6307-TS
REVISION (9)
24th October 2018

Last printed: 12 November 2018

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- Complete and return the attached response form to 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.

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**

Pure Armstrong

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# Response Form

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

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*n/a not applicable

Please check ALL appropriate boxes.

- ❑ I have read and understand the recall instructions provided in the Field Safety Notice.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ I have read the software notes and updated the software

Indicate disposition of recalled product:

- ❑ Updated software (*specify quantity and date)*
- ❑ Analyser decommissioned and does not require update.

**Customer Details**

| | |
|---|---|
| Company Name | |
| Address | |

**Total Quantity**

| | |
|---|---|
| Received | |
| Distributed | |



Form No. 12187-QA
REVISION (0)
25th October 2018

RANDOX

## Response Form

Randox Laboratories Ltd
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**Area of Distribution** (To be completed by Distributors and Randox Offices)

- ❑ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*); **OR**
- ❑ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Have you been notified of any adverse events associated with recalled product?

- ❑ YES
- ❑ NO

If yes, please explain: _____

| Consignee | Country | Quantity Received | Analyser Serial Number | Replacements Required |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

| | | | |
|---|---|---|---|
| Completed By | Print Name:<br><br>Signature: | Date | |
| Contact Telephone | | | |
| Contact Email | | | |

Complete and return the response form to technical.services@randox.com within five working days.



Form No. 12187-QA
REVISION (0)
25th October 2018