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: 4th Nov 2021

Complaint Reference: REC540

Action Type: Device Modification

Detail on Affected Devices:

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

Device Name	Catalogue Number	GTIN
Evidence Investigator	EV3602, EV3602R, EV4187	05055273209952

Reason for Action:

Randox have received reports of the software issues detailed in the software corrections section. Those numbered 1 & 2 originate from customer complaints and are applicable to all the test menu arrays, number 3 was discovered during internal testing and is applicable to the STI multiplex array only, number 4 was discovered during internal manufacturing QC testing and does not affect instruments in the field.

The Evidence Investigator software version 2.2.0 is now available with corrections, updates and known issues detailed below:

Form No. 6307-TS
REVISION (10)
4th Feb 2019

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Software Corrections:

These are the corrections made within the software as a result of customer queries & complaints in previous releases of the Evidence Investigator software

1	**Controls not displayed in QC display** Unable to view Control data within QC Display screen for 2 batches of QC with the same lot number but 2 distinct batch barcodes. **Reason For Action** : Customer Complaint
2	**Incorrect User Acccount Id of 0 being permitted if the operator had selected to "Cancel" the "Change Password" function during first initialisation.** The software prompts the operator to change their password on their first login – however the operator avoids doing this and selects Cancel. The software was then allowing an unchecked access to the system and any runs completed during this session were then not permitted for viewing (as the user ID was set to 0 at the time of running). Then when the operator correctly changes their password and accesses the system, they cannot see the sample results which were ran during the unchecked session. **Reason For Action** : Customer Complaint
3	**LIMS error flag - STI Multiplex Array** The software incorrectly sends out an additional unnecessary error flag "out of range " against the STI sample to the LIMS Host. The actual sample results transmitted are correct and the results reported on the UI and Reports are also correct. **Reason For Action** : Internal Testing
4	**Investigator Machine QC – Calibration User Details** Does not affect field instruments, issue only seen during initial QC of analyser during manufacturing. Calibration Graphs Report fails to detail the username of the operator who ran the curve if this is the very first report ever generated on the system. **Reason For Action** : Internal QC Testing

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Software Updates:

These are new features made within the software as a result of customer feedback, continuous product improvement & development of new arrays.

5	**Inclusion of the Bovine Pathogen Array** The Bovine Pathogen Array Milk is a qualitative assay which detects antibodies against 9 analytes representative of 6 economically important bovine pathogens.
6	**Inclusion of the SARS-CoV-2 IgG Array** The Randox SARS-CoV-2 IgG Array utilises patented biochip technology to simultaneously detect IgG antibodies against both leading COVID-19 diagnostic antigens; Spike Receptor Binding Domain (RBD) and Nucleocapsid protein (NP).
7	**Update to STI / COVID 19 Calculation** Update to the STI calculations to produce an "Inconclusive – Repeat" result where a result cannot be calculated.
8	**Ability to export STI COVID 19 Results** Inclusion of the ability to export results relating to STI & COVID 19 arrays to .csv format.
9	**Update to Food Diagnostic Qualitative Arrays** Inclusion of the ability to allow operators to unselect an assay(s) on any food diagnostics qualitative array during the sample entry process.
10	**Update of Reports from QRP to PDF** All reports generated within the Evidence Investigator software have been updated to be generated in .PDF file format.
11	**Ability to print Result History at once** The following report options are available: • Multiple Reports: Prints the selected sample(s) to the one report print out. Separate samples are listed below each other. • Individual Reports (Separate Documents): Prints the selected samples to their own respective reports (no two samples on the one report page) and displays them to the operator to view and print on a one by one basis. • Individual Reports (All): Prints the selected samples to their own respective reports (no two samples on the one report page) but allows the operator to view and print them in a group at the one time. Note: Report layout options are array dependent.
12	**Update of Archiving Report Format** The format and layout of the archived reports have been updated to be in a similar format and layout to the result history report for the associated array. Note: This software change is array dependent. The archived report for any arrays that are not affected by this change will remain in the original archived report form.
13	**Update to QC Display to allow Date Range Selection** Inclusion of the ability to select a customisable Date Range for displaying QC data in addition to the original Daily (1 day) or Cumulative (180 days). Note: Selecting Daily or Cumulative will only display QC data ran in the past 180 days.

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14	**Inclusion of the ability to Save and Load Worklists** Inclusion of functionality into the Investigator software to allow operators to Save and Load worklists within the Sample Entry Screen via F2 and F3 keyboard shortcuts. This will mitigate against worklist loading errors and allow faster loading of repeatable worklists.
15	**Inclusion of additional checks during Sample Entry** Inclusion of additional checks to ensure the Array and Concentration disc has been loaded on the system correctly prior to running calibrations, controls or samples. Inclusion of additional checks during the Sample Entry process to ensure all camera files required are present on the system.
16	**Inclusion of the Russian Language** Inclusion of the ability to view the Evidence Investigator UI and Reports in the Russian language.
17	**Update to Admin Control form and Login Attempts** Inclusion of the ability for the system administrator to customise configurable analyser settings: User Settings, Password Settings, Report Settings, General Settings.

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Known issues within the release of this software not corrected:

These are the issues that were detected during software testing of the V2.2.0 release and which will be deferred for resolution in a future release

18	**Launch Robotic Cycle** The "Launch Robotic Cycle" button within the Service screen is enabled prior to the initialisation of the analyser. If power to the analyser robotics is not established the operator will be alerted to a robotic communication issue. Note: This feature is used for troubleshooting by authorised Randox personnel only and is not used or required in routine operation of the analyser. **Remedial action**: Operator should initialise the analyser prior to launching the robotic cycle. Reason For Action : Discovered during Software Testing of V2.2.0
19	**SARS-CoV-2 IgG Sample Classification Displayed in Duplicate on Reports** The summary Sample Classification associated with SARS-CoV-2 IgG sample results is displayed in duplicate against each analyte result instead of a single Sample Classification on the Result Reports. The Sample Classification is still calculated and assigned correctly. Note: - Only a single Sample Classification is displayed within the Result History screen for the selected sample. **Remedial action**: Operators should note that the summary Sample Classification duplicated & displayed against each analyte on the Report is correct. Operators can also refer to the single Sample Classification within the Result History screen. Reason For Action : Discovered during Software Testing of V2.2.0
20	**Russian Translations** Operators should refer to the Suggested Russian Text detailed in the software release notes. **Remedial action:** Operators should refer to the Suggested Russian Text. Reason For Action : Discovered during UAT Testing of V2.2.0

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Risk to Health:

No risk to health, possible delay in reporting results.

Action to be taken:

- Review the software release notes provided for further information.
- Please complete the mandatory software upgrade. Please contact technical.servies@randox.com for the OneDrive link to the software update files.
- Complete and return the response form 12187-QA 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

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Response Form

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Please complete this form *even if you do not have any affected stock*.

Date Issued: 4th Nov 2021
Complaint Reference: REC540 **Action Type:** Device Modification

Detail on Affected Devices:

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

Device Name	Catalogue Number	GTIN
Evidence Investigator	EV3602, EV3602R, EV4187	05055273209952

Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ❑ no affected stock
- ❑ instrument updated

Customer Details

Company Name	
Address	

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Total Quantity

Received	
Distributed	

Completed By	Print Name: Signature:	Date	
Contact Telephone			
Contact Email			

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

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

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PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

- ❑ 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)

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

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

- ❑ YES
- ❑ NO

If yes, please explain: _____