



URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Ref No: PFSN-SBN-CPS-2018-011
Date: 03/09/2018
Type of Action: Field Safety Corrective Action (FSCA)

Product Affected: Accu-Chek ® Inform II system
CoaguChek Pro II system
CoaguChek ® XS Plus system
CoaguChek ® XS Pro system
cobas h 232 POC system
cobas h 232 POC system (scanner version)

Product Name	Product code
Accu-Chek Inform II Instrument	05060311001
Accu-Chek Inform II Instrument with RF card	05060303001
Accu-Chek Inform II Base Unit	05060290001
Accu-Chek Inform II Base Unit Hub	05888760001
CoaguChek Pro II Kit W-LAN	07210841190
CoaguChek Pro II Kit without W-LAN	07237944190
CoaguChek XS Plus Kit International	04800842190
CoaguChek XS Plus Care kit	05021537001
CoaguChek XS Pro Kit International	05530199190
cobas h 232 scanner version	04901142190
cobas h 232	04901126190
cobas h 232 Kit scanner-version with battery pack	04901142018
Handheld Base Unit	04805658001

Summary of Issue

We want to inform you about the availability of upcoming cybersecurity updates for the following Roche Diagnostics products: Accu-Chek Inform II, **cobas h** 232, CoaguChek Pro II, CoaguChek XS Plus / XS Pro systems.

Reason for Notice

Roche Diagnostics is committed to continuously increase cyber security of its products. As part of this effort, we plan to release software updates that could prevent or reduce risk of products being exploited by cyber attackers. Potential risks of cyber-attack include compromised system confidentiality, availability and integrity.

The efforts to perform a successful cyber-attack of our devices were assessed to be highly complex, as attackers with criminal intent would need to physically access, manipulate our

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devices, or hack into the healthcare network, to successfully exploit potential vulnerabilities. Hence, the likelihood to impact patient safety from such exploitation is assessed to be remote to theoretical.

At the time of the Field Safety Notice, no public exploitation of these security vulnerabilities is known.

Actions taken by Roche Diagnostics

Roche Diagnostics plan to release the following software updates:

Product Code	Product Name	New Software	Date of release
05060311001	Accu-Chek Inform II Instrument serial number <14000	03.06.00	November
05060303001	Accu-Chek Inform II Instrument with RF serial number <14000	03.06.00	November
05060311001	Accu-Chek Inform II Instrument serial number >14000	04.03.00	November
05060303001	Accu-Chek Inform II Instrument with RF serial number >14000	04.03.00	November
05060290001	Accu-Chek Inform II Base Unit	03.01.04	November
05888760001	Accu-Chek Inform II Base Unit Hub	03.01.04	November
07210841190	CoaguChek Pro II Kit W-LAN	04.03.00	November
07237944190	CoaguChek Pro II Kit without W-LAN	04.03.00	November
04800842190	CoaguChek XS Plus Kit International	03.01.06	November
05021537001	CoaguChek XS Plus Care kit	03.01.06	November
05530199190	CoaguChek XS Pro Kit International	03.01.06	November
04901142018	cobas h 232 Kit (scanner, battery pack)	03.01.03	November
04901142190	cobas h 232 Kit (scanner) with serial number <KS04XXXXX	03.01.03	November
04901126190	cobas h 232 with serial number <KQ03XXXXX	03.01.03	November
04901142190	cobas h 232 Kit (scanner) with serial number ≥KS04XXXXX	04.00.04	November
04901126190	cobas h 232 with serial number ≥KQ03XXXXX	04.00.04	November
04805658001	Handheld Base Unit	03.01.04	November

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Actions to be taken by the customer/user

Medical device cybersecurity is a shared responsibility among multiple stakeholders including health care facilities, providers, and manufacturers.

Roche Diagnostics recommends an update of your device software to further improve the cyber security of the device, according to the table above. Since the likelihood to impact patient safety from such exploitation is assessed to be remote to theoretical an update to your device is **not** mandatory.

In general, Roche Diagnostics would like to remind you to put the following measures in place to increase your cyber security:

For connected devices (Ethernet and Wi-Fi) –

- Restrict network and physical access to the device and attached infrastructure by enabling the device security features
- Protect connected endpoints from unauthorized access, theft and malicious software
- Monitor the system and network infrastructure for suspicious activity and report a suspected compromise according to your local policy

For non-connected devices -

- Protect from unauthorized access, theft and manipulation

Please contact Roche Diagnostics Technical support if you have any further questions or concerns.

Please complete and return the **Acknowledgement Form** which accompanies this **Field Safety Notice** by **17th September 2018**

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments

PFSN-SBN-CPS-2018-011 Acknowledgement form

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This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the [Roche Dialog Portal](#)

If you require any further information please email

burgesshill.cyberfsn@roche.com

(non urgent enquiries)

Or, alternatively for urgent enquiries, contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

Selecting option 4, then option1

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