

Urgent Field Safety Notice

SBN-CPS-2018-011

CPS / Point of Care
Version 2
Aug-2018

Cybersecurity updates in Accu-Chek® Inform II system, cobas h 232 POC system, CoaguChek® Pro II system, CoaguChek® XS Plus / XS Pro systems

Product Name	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)	
Production Identifier (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 Plus Kit Japan	04800842174
	CoaguChek XS Pro Kit International	05530199190
	CoaguChek XS Pro Kit USA	05530199160
	cobas h 232 scanner version	04901142190
	cobas h 232	04901126190
	cobas h 232 Kit scanner-version with battery pack	04901142018
	Handheld Base Unit	04805658001
	Handheld Base Unit US	04805658160
Type of Action	Field Safety Corrective Action (FSCA)	

Cybersecurity updates in Accu-Chek® Inform II system, cobas h 232 POC system, CoaguChek® Pro II system, CoaguChek® XS Plus / XS Pro systems



Dear Valued Customer,

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.

Description of Situation

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 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:

[COUNTRY ACTION: You are allowed to modify the column "Date of release" according to your local release schedules and to remove the line containing product not locally available]

Product Code	Product Name	New Software	Date of Release (Global Release Schedule) 2018
05060311001	Accu-Chek Inform II Instrument serial number < 14000	03.06.00	September
05060303001	Accu-Chek Inform II Instrument with RF serial number < 14000	03.06.00	September
05060311001	Accu-Chek Inform II Instrument serial number > 14000	04.03.00	October
05060303001	Accu-Chek Inform II Instrument with RF serial number > 14000	04.03.00	October
05060290001	Accu-Chek Inform II Base Unit	03.01.04	September
05888760001	Accu-Chek Inform II Base Unit Hub	03.01.04	September
07210841190	CoaguChek Pro II Kit W-LAN	04.03.00	October
07237944190	CoaguChek Pro II Kit without W-LAN	04.03.00	October
04800842190	CoaguChek XS Plus Kit International	03.01.06	September

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05021537001	CoaguChek XS Plus Care kit	03.01.06	September
04800842174	CoaguChek XS Plus Kit Japan	03.01.06	September
05530199190	CoaguChek XS Pro Kit International	03.01.06	September
05530199160	CoaguChek XS Pro Kit USA	03.01.06	September
04901142018	cobas h 232 Kit (scanner, battery pack)	03.01.03	October
04901142190	cobas h 232 Kit (scanner) with serial number <KS04XXXXX	03.01.03	October
04901126190	cobas h 232 with serial number <KQ03XXXXX	03.01.03	October
04901142190	cobas h 232 Kit (scanner) with serial number ≥KS04XXXXX	04.00.04	October
04901126190	cobas h 232 with serial number ≥KQ03XXXXX	04.00.04	October
04805658001	Handheld Base Unit	03.01.04	September
04805658160	Handheld Base Unit US	03.01.04	September

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 your local Roche Diagnostics office if you have any further questions or concerns (contact details below).

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied. (If appropriate).

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Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com