

# Urgent Field Safety Notice

*SBN-CPS-2018-011*

CPS / Point of Care  
Version 2  
Aug-2018

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

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|--|--|--|
| <b>Product Name</b>  | Accu-Chek <sup>®</sup> Inform II system<br>CoaguChek Pro II system<br>CoaguChek <sup>®</sup> XS Plus system<br>CoaguChek <sup>®</sup> XS Pro system<br><b>cobas h</b> 232 POC system<br><b>cobas h</b> 232 POC system (scanner version)  |  |
| <b>Production Identifier<br/>(Product name/Product code)</b> | Accu-Chek Inform II Instrument<br>Accu-Chek Inform II Instrument with RF card<br>Accu-Chek Inform II Base Unit<br>Accu-Chek Inform II Base Unit Hub<br>CoaguChek Pro II Kit W-LAN<br>CoaguChek Pro II Kit without W-LAN<br>CoaguChek XS Plus Kit International<br>CoaguChek XS Plus Care kit<br>CoaguChek XS Plus Kit Japan<br>CoaguChek XS Pro Kit International<br>CoaguChek XS Pro Kit USA<br><b>cobas h</b> 232 scanner version<br><b>cobas h</b> 232<br><b>cobas h</b> 232 Kit scanner-version with battery pack<br>Handheld Base Unit<br>Handheld Base Unit US | 05060311001<br>05060303001<br>05060290001<br>05888760001<br>07210841190<br>07237944190<br>04800842190<br>05021537001<br>04800842174<br>05530199190<br>05530199160<br>04901142190<br>04901126190<br>04901142018<br>04805658001<br>04805658160 |
| <b>Type of Action</b>  | 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                                      |

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



|             |  |          |           |
|-------------|--|----------|-----------|
| 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 | <b>cobas h 232</b> Kit (scanner, battery pack)                 | 03.01.03 | October   |
| 04901142190 | <b>cobas h 232</b> Kit (scanner) with serial number <KS04XXXXX | 03.01.03 | October   |
| 04901126190 | <b>cobas h 232</b> with serial number <KQ03XXXXX               | 03.01.03 | October   |
| 04901142190 | <b>cobas h 232</b> Kit (scanner) with serial number ≥KS04XXXXX | 04.00.04 | October   |
| 04901126190 | <b>cobas h 232</b> 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).

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



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

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Email name@roche.com