

Urgent Field Safety Notice

SBN-RPD-2015-020

RPD / Point of Care Handheld Platform
Version 3
26-Jan-2016

Handheld Platform – USB Communication Data Loss

Product Name			
Accu-Chek Inform II Base Unit	05060290001		see text body
Handheld Base Unit	04805658001		see text body
Handheld Base Unit USA	04805658160		see text body
Roche HBU/BU Control Panel	N/A		SW <=03.00.00
Accu-Chek Inform II meter+RF	05060303001		N/A
Accu-Chek Inform II meter	05060311001		N/A
cobas h 232	04901126190		N/A
cobas h 232 scanner version	04901142190		N/A
CoaguChek XS Pro Int'l	05530199190		N/A
CoaguChek XS Pro USA	05530199160		N/A
CoaguChek XS Plus Int'l	04800842190		N/A
CoaguChek XS Plus Japan	04800842174		N/A
CoaguChek Pro II WLAN	07210841190		N/A
CoaguChek Pro II	07237944190		N/A

Type of Action Field Safety Corrective Action (FSCA)

Dear Valued Customer,

The purpose of this notification is to inform you about the potential risk of data loss using USB communication, escalated by three (3) complaints.

Some Accu-Chek Inform II Base Units (BU) and Handheld Base Units (HBU), used for CoaguChek Professional meters and cobas h232 meters, might produce transmission errors between the meter and the data management system (DMS; e.g. **cobas IT** 1000 or any other 3rd party software). The transmission errors present in the form of data loss. This could happen, in rare cases, when the BU/HBU is connected via a USB to a PC.

If your BU/HBU is connected via Ethernet or if you use Wi-Fi, you will not experience this issue.

If your BU/HBU is connected to a PC via USB, the data loss may cause invalid data exchange. For example, in the case of the Accu-Chek Inform II meter, this is indicated by numerous messages sent from the meter to the DMS in the form of “unexpected SW failure 11800” events.

Please note that the error message “unexpected SW failure 11800” is quite unspecific. It might have other causes and is therefore no clear indicator for the data loss.

Handheld Platform – USB Communication Data Loss

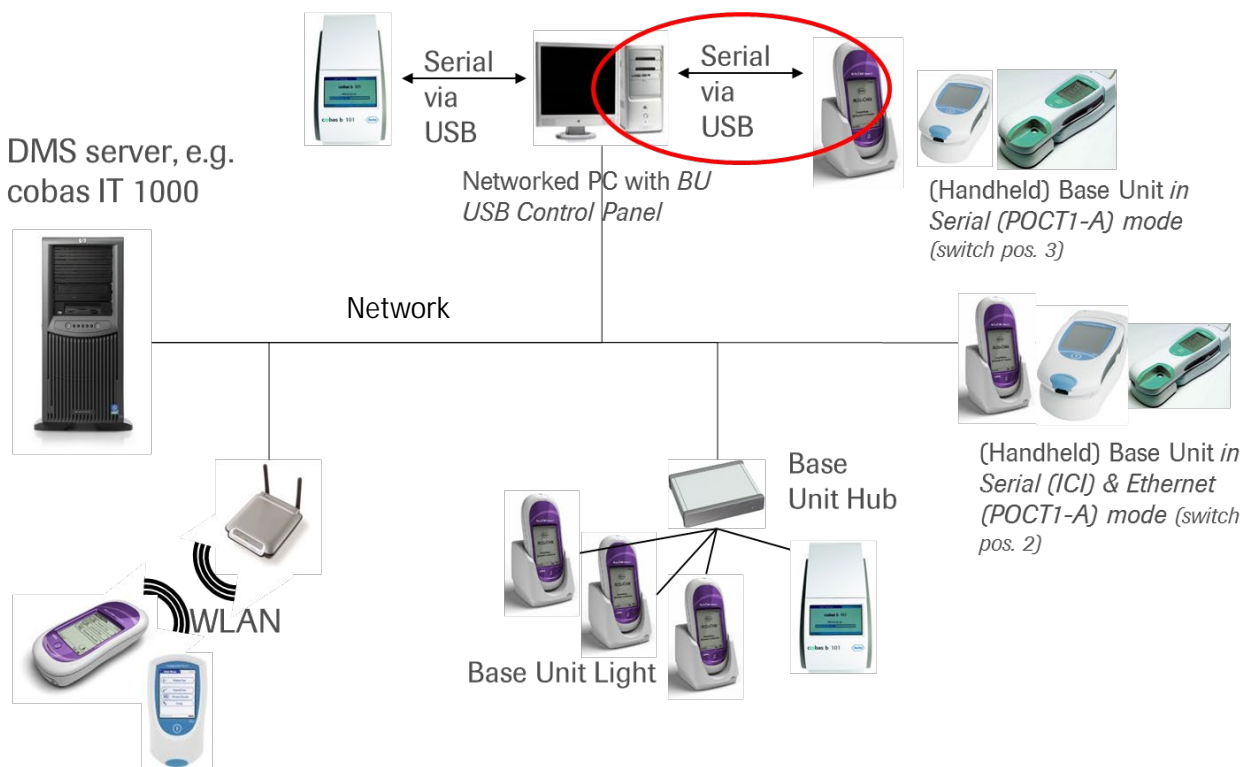
Description of Situation

Introduction

There are various connectivity options for Handheld Platform meters (Accu-Chek Inform II, CoaguChek Professional and cobas h232). Please refer to the graphic below.

Only the connection via USB to a PC is affected by this issue.

Communication via Ethernet (Local Area Network, LAN; Wide Area Network, WAN) or wireless local area network (WLAN) is not affected.



Data transmitted include but is not limited to:

- Patient lists
- Operator lists
- Reagent data (lot, expiry, calibration)
- Configuration
- Results

Handheld Platform – USB Communication Data Loss

Issue

- All three (3) complaints mentioned above were reported for the **Accu-Chek Inform II** meter/base unit when connected to **cobas IT 1000** using the USB connectivity option.
- The three (3) cases have been reported from a single site. It was observed that a glucose result for an individual patient, received in **cobas IT 1000**, differed from the result stored in the respective meter.
- No complaints were received so far for the **CoaguChek Professional** or **cobas h 232** meters (internal Roche review indicates that these might be potentially affected), nor for the Ethernet or WLAN option of any Handheld Platform meters, nor for any of our Handheld Platform meters when connected to a 3rd party DMS.

Other issues that were found to be related to the same root cause include:

- Result entry appears in **cobas IT 1000**, but without numeric result (data field is empty)
- General connectivity concerns (slow or delayed data transmission)
- Accu-Chek Inform II meters have numerous (unspecific) “unexpected SW failure 11800” events. Those were identified in the **cobas IT 1000** “instrument status” screen.

Units Concerned

Some but not all of the Accu-Chek Inform II Base Units and some but not all of the Handheld Base Units are affected. Please refer to the table below to see the list of affected base units.

If the BU / HBU serial number is within this range and it is connected via USB, this notice affects you.

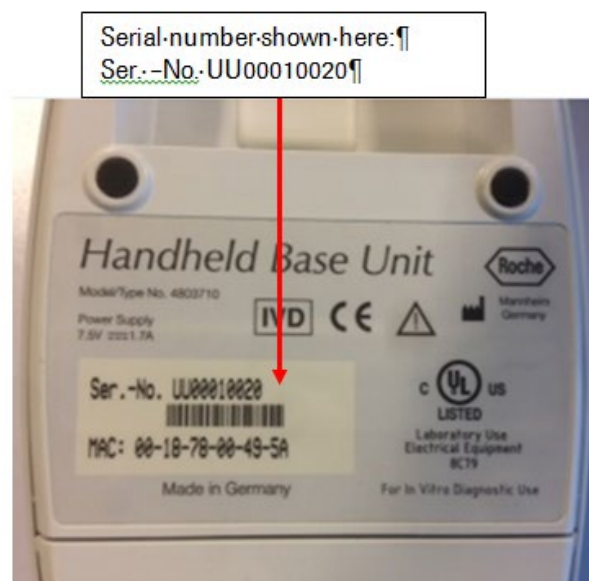
NOTE: You can identify the affected base units by the serial number that can be found on the back label of the Accu-Chek Inform II Base Unit and/or the Handheld Base Unit:

Serial number identification

For Accu-Chek Inform II Base Units:



For Handheld Base Units:



Handheld Platform – USB Communication Data Loss

The following table gives an overview of affected serial numbers:

Serial number range is...	Accu-Chek Inform II Base Unit	Handheld Base Unit International	Handheld Base Unit USA
NOT affected	(low range not applicable) UU41122742 and above	UU00007002 and below; UU00019705 and above	UU00007002 and below; UU00018503 and above
100% affected	UU41000000 - UU41064963	UU00007003 - UU00017129	UU00007003 - UU00017129
Potentially affected (please contact your local Roche support for confirmation*)	UU41064964 - UU41122741	UU00017130 - UU00019704	UU00017130 - UU00018502

* In case you have Accu-Chek Inform II Base Units and/or Handheld Base Units with a serial number listed under “potentially affected”, please contact your <local Roche affiliate> to receive details that help you identify if your base units are affected or not.

Include if applicable for your country the following sentence in italics:

If you need lot number information in addition to serial numbers to identify whether you have affected base units, please contact < local Roche affiliate >.

An alternative option to identify affected base units is to check the hardware revision in the file called “status.log”.

- This file can be found on the Accu-Chek Inform II Base Unit and Handheld Base Unit mass storage drive.
- Access the USB mass storage drive of the base unit in configuration mode.
- For instructions to access the mass storage drive, please refer to the operator documentation provided by Roche (Operator’s Manual for the Handheld Base Unit, Package Insert for the Accu-Chek Inform II Base Unit).
- Affected by the issue in scope of this letter are base units with hardware version **HW=4.3**.
- On a Windows computer, the status.log file opens within a standard text editor application. You can either scroll the file or use the “search” or “find” function of your application to find one of the following entries:

```
dd.mm.yyyy   hh:mm:ss   Handheld Base Unit version info: BL=01.00.02 KN=01.02.03
RF=01.02.01 AP=03.01.01 HW=4.3 BOM=0432B HW_IDENT_NO=5076544001 SN=00000000xxxxxxxx
```

Frequency of Occurrence

- The issue was reported at one customer site only.
- Only those customers that use USB communication functionality are affected

Root Cause

A software failsafe feature which is built into the **PC driver** (“Roche HBU/BU Control Panel”) to assure correct data transmission does not work appropriately with the currently available versions of the driver.

Handheld Platform – USB Communication Data Loss

Actions taken by Roche Diagnostics

Roche Diagnostics is developing a new version of the “Roche BU/HBU Control Panel” which must be installed on the PC connecting the BU/HBU via USB. The target date for release of this new version from Roche’s development department is Q1, 2016.

Actions to be taken by the customer/user

Customers currently not using the USB connectivity option don’t need to take any immediate action.

Roche will provide new “Roche HBU/BU Control Panel” software to be installed on the PC that has the BU/HBU connected to it via USB. This new software version must be installed.

You should not use the USB connectivity option without further precautions until the new software version is installed.

- Please check the serial number of any BU/HBU that is connected to a PC via USB.
- Identify your preferred workaround listed below for any affected BU/HBU.

Roche suggest that one of the following workarounds is implemented to avoid the problem:

- Change the connectivity method from USB to Ethernet or Wi-Fi.
- Install a device that can be used to improve the USB signal to significantly reduce the potential transmission errors. The device is called an USB hub/active repeater and one of these is required per USB connection.

Please note: It will still be necessary for the connected PC to be updated to the new version of the software when it is available.

- Due to some variances in Base Unit and computer hardware, only specified USB hubs or active USB-repeaters can address the issue. Please refer to < local Roche affiliate > for assistance to obtain suitable USB hubs or repeater cables.

The USB connectivity must not be used or introduced until your system is upgraded to the new SW version.

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected BU/HBU have been distributed/supplied.

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.

Kind regards,

Handheld Platform – USB Communication Data Loss

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com