



## Analyzer Bulletin

### Handheld Base Unit for CoaguChek® XS Plus and CoaguChek XS Pro Systems – USB Communication Data Loss

#### Issue

Handheld Base Units (HBUs) are an optional component of the CoaguChek® XS Plus and CoaguChek XS Pro meters for charging and to enable connectivity. In rare cases, HBUs may produce transmission errors in the form of data loss when connected by USB communication to the data management system (e.g., **cobas** IT 1000 or third party software). This happens in rare cases of data transmission via USB connection to a PC (USB mode 3).



NOTE

**Only communication via USB is affected by this issue. There is no impact to data transmission via network connection. Regardless of the communication method used, the result displayed on the meter is correct.**

This error may produce invalid data transmission. Data transmitted include but are not limited to:

- Patient list
- Operator list
- Test strip data (lot and expiration date)
- Configuration
- Results

Other potential consequences include:

- Result entry is generated in **cobas** IT 1000 (or third party software) but without numeric result (data field is empty)
- General connectivity concerns (slow or delayed data transmission)

Affected HBUs were produced between September 2008 and August 2010. Some, but not all, of the HBUs shipped during this time are affected. The following table gives an overview of affected serial numbers:

Product/ Catalog Number	All Units in Serial Number Range are Affected	Units in Serial Number Range are Potentially Affected
Handheld Base Unit/ 04805658160	UU00007003 through UU00017129	UU00017130 through UU00018502



NOTE

**Serial numbers UU00007002 and below and UU00018503 and above are not affected by this issue.**

over...

- CoaguChek XS Pro
- CoaguChek XS Plus

## Identifying the Serial Number on the Handheld Base Unit

---

See the picture below for the HBU serial number location:

### Serial Number Location



An alternative option for determining if your handheld unit is affected, is to check the hardware version in the “status.log” file.

- This file can be found on the HBU’s mass storage drive.
- Access the USB mass storage drive of the base unit in configuration mode.
- For instructions on how to access the mass storage drive, please refer to the operator documentation provided in the Operator’s Manual.
- HBUs with hardware version “HW=4.3” are affected by the issue.
- On a Windows® computer, the “status.log” file opens within a standard text editor application. You may either scroll through the file or use the “search” or “find” function of your application to find the following entry:

```
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
```

If you are unable to determine if your HBU is affected by this issue, please contact Roche Diagnostics Point-of-Care Technical Service at 1-800-428-4674.

## Root Cause

---

If a specific electronic part on the base unit main circuit board is close to its manufacturing tolerance limits and still within specification, this specific part might disturb the USB signal. In this case, transmission errors could occur.

In case of a transmission error, the USB driver used with the customer’s computer requests the data to be re-transmitted. This data re-transmission is designed into the base unit. Unfortunately, the USB driver requests a data package that is too large and is not available on the base unit. This results in the observed data loss.

## **Interim Solution**

---

Roche is currently developing an update to the control panel software to resolve this issue. Until the new software is available, do not use USB connectivity if your HBU is affected by this issue; switch the connectivity method to Ethernet (TCP/IP).

We will notify you as soon as the updated software or an alternative solution is available. We are targeting availability by the end of March 2016.

## **Clinical Significance**

---

Although occurrence is rare, this issue can lead to data loss, or in the worst case, to an erroneous assignment of the patient data (patient mismatch). In case of a patient mismatch, taking into account the difficulty in detecting the issue, the potential for a serious medical adverse event cannot be excluded.

## **Actions Required**

---

- If you are currently using USB connectivity, follow the instructions outlined in this Analyzer Bulletin to determine if your HBU is affected by this issue.
- Until the new software is available, do not use USB connectivity if your HBU is affected by this issue; switch the connectivity method to Ethernet (TCP/IP).
- If your facility has distributed the affected product to another site, please ensure this Analyzer Bulletin is provided to that site.
- Look for future communications regarding the resolution of this issue.
- File this Analyzer Bulletin for future reference.

## **Questions**

---

Please contact Roche Diagnostics Point-of-Care Technical Service at 1-800-428-4674 if you have questions about the information contained in this Analyzer Bulletin.

COAGUCHEK and COBAS are trademarks of Roche.

WINDOWS is a trademark of Microsoft.