

Urgent Field Safety Notice – Update2

Notice Ref No:	SB-RPD_2013_06
Document Date:	08 May 2013
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	CoaguChek XS Plus CoaguChek XS Pro
SYSTEM AFFECTED:	See above
MATERIAL NUMBERS:	04800842xxx (CoaguChek XS Plus): serial nos. < 90000 05021537001 (CoaguChek XS Plus): serial nos. < 90000 05530199xxx (CoaguChek XS Pro): serial nos. < 6011000
SERIAL NO (IF APPLICABLE):	Serial numbers < 90000 for CoaguChek XS Plus; Serial numbers < 6011000 for CoaguChek XS Pro
SUMMARY OF ISSUE:	ERROR 6 might require an urgent alternative INR measurement due to possibly high INR values
ACTION REQUIRED:	Under certain circumstances with ERROR 6, patients must contact their physician immediately
CONTACTS:	Technical Services: Country:

Reason for notice:

User information for the CoaguChek® XS Plus and the CoaguChek® XS Pro System

Action required:

Dear Sir or Madam,

You use our CoaguChek® XS Plus and/or CoaguChek® XS Pro system to monitor your patients' anticoagulation therapy.

As you know, the CoaguChek® XS Plus/CoaguChek® XS Pro instrument measures your patients' coagulation status up to an INR value of 8.0. It is known that, in very rare situations, INR values greater than 8.0 can occur – for example if the patient is undergoing antibiotic treatment or chemotherapy. The CoaguChek® XS Plus/CoaguChek® XS Pro instrument detects these very high values and displays the following two messages for your patients' protection:

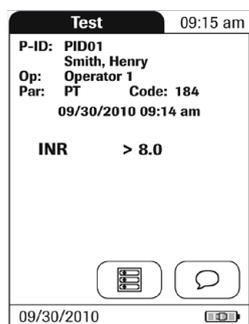


Fig. 1

or

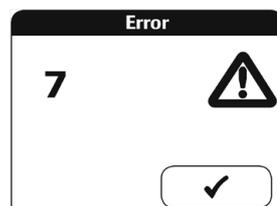


Fig. 2

The user manual informs you that an "error 7" (Fig. 2) could indicate a very high INR value and that, after repeating the test with the same result, you should try an alternative test method.

In April 2013, we were made aware of a case in Norway in which antibiotic treatment resulted in a patient having an INR value greater than 10. However, the CoaguChek® XS instrument displayed an "error 6". A patient looking up this error code in the user manual receives the information that an error has occurred in the measurement process. Although a very high INR value is practically excluded as a reason for this error message, we consider it wise to point out that a very high INR value (greater than 10) could be another reason for this error message being displayed.

We are so far unaware of any single case, anywhere in the world, in which this error has been produced on a CoaguChek® XS Plus or CoaguChek® XS Pro instrument. We are nevertheless taking the precaution of informing you about the above situation, because we cannot exclude the possibility that this could occur on CoaguChek® XS Plus instruments with serial numbers lower than UQ 0090000 and CoaguChek® XS Pro instruments with serial numbers lower than U7 6011000. In this event, you would

see the following error message:

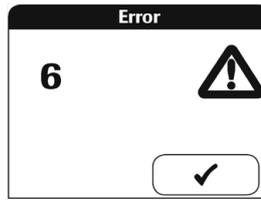


Fig. 3

The CoaguChek® XS Plus instruments with a serial number equal to or higher than UQ 0090000 and the CoaguChek® XS Pro instruments with a serial number equal to or higher than U7 6011000 are not affected!

What do you have to do if your CoaguChek® XS Plus instrument (<UQ 0090000) or your CoaguChek® XS Pro instrument (<U7 6011000) displays “error 6”?

If this happens, the most likely cause is that an error has occurred in the measurement process. Please turn off the CoaguChek® XS instrument, remove the test strip and repeat the measurement with a new test strip. Make sure that you do not squeeze the patient’s finger while taking the blood and that you do not touch the test strip during the measurement – these are the two most frequent causes of an “error 6”. If you follow the correct procedure and “error 6” is displayed again, please contact our CoaguChek® Customer Service Center (telephone number at the end of the letter) and use a different test method to check the result.

This is particularly important for you:

- All CoaguChek® instruments continue to perfectly measure your patients’ INR values – even if they are undergoing antibiotic treatment or chemotherapy. The CoaguChek® XS instruments never produce incorrect values.
- 99.99% of cases in which an “error 6” is displayed result from an incorrect measurement process. Since the CoaguChek® XS instrument was introduced in 2006, the Norwegian case is the only case anywhere in the world in which an INR value greater than 10 has produced an “error 6”.

Our staff at the CoaguChek® Customer Service Center will be happy to answer any questions you may have regarding this letter. You can call the CoaguChek® Customer Service Center on (date/time) on (Telephone number).

Yours faithfully