

URGENT MEDICAL DEVICE CORRECTION

CoaguChek® Patients

CoaguChek XS Meters for Patient Self-Testing Use (CoaguChek XS PST) — Possible Misinterpretation of Displayed Measuring Units

This Urgent Medical Device Correction (UMDC) **only** affects patients using:

Product
CoaguChek XS meter

If you are currently using the CoaguChek Vantus meter, please DISREGARD this document.



The CoaguChek XS PT test strips are not affected by this issue.

NOTE

Issue

You are receiving this Urgent Medical Device Correction (UMDC) because records indicate that you were shipped a CoaguChek XS PST meter. This document provides important information about your meter. **Please read this entire document.**



The CoaguChek XS PST meter is provided to U.S. customers pre-set to the measuring unit INR. There are two additional measuring units on the meter: %Quick (%Q) and Seconds (Sec). In the U.S., the most accepted unit of measure is INR. Unless your physician has instructed you to monitor in a unit other than INR, results should be reported in INR.

NOTE

Roche has been made aware of the following issues:

- The measuring unit of some patient CoaguChek XS PST meters was inadvertently changed by the operator during use from INR to %Quick or Seconds, resulting in a CoaguChek XS test result perceived to be different from the laboratory result in INR.
- A value displayed in %Quick or Seconds was misinterpreted by a patient as an INR result, and the misinterpreted result was significantly higher than the patient's actual INR.
- In the above instances, the result produced in %Quick or Seconds was not alleged to be inaccurate.

over...

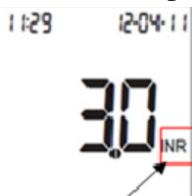
CoaguChek XS PST

Issue, continued

The current User Manual for your meter does not contain instructions on how to change measuring units on the CoaguChek XS PST meter. This UMDC provides instructions on how to ensure your meter is displaying INR results. Roche is updating the User Manual and the package insert labeling for the test strips accordingly.

Actions Required

- When testing for INR, **always confirm that “INR” is displayed next to the result after each test.** Reporting your result in a measuring unit other than INR could lead to an incorrect assessment of appropriate treatment and potential for harm.



- Follow the instructions provided in the ***Patient Instructions*** section of this UMDC to ensure that the measuring unit result is set to INR. Refer to these instructions when adjusting the date/time in your meter and when the measuring unit needs to be reset to INR. Any measurement unit set-up choices other than INR must be authorized by your doctor.
- If your meter is displaying a result in a different unit than INR and you are unable to reset the measuring unit to INR after following the instructions in the ***Patient Instructions*** section of this UMDC, contact the **Roche Customer Support Center at 1-800-428-4674** for assistance.
- This Urgent Medical Device Correction (UMDC) serves as supplemental labeling. File this UMDC with your User Manual for future reference.

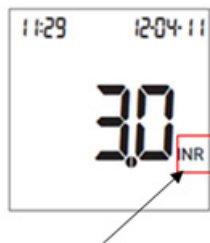
Patient Instructions

Check the Measuring Unit for Your INR Test Result



The current result can be changed to a different unit without actually changing the settings for measuring units on the meter.

1. With the meter powered off, press the **M** button and confirm your last test result is displayed as “**INR.**”



the measuring unit is displayed next to the result

2. Press the **M** button again to confirm the previous test result also displays as “**INR.**”

Patient Instructions, continued

Check the Measuring Unit for Your INR Test Result, continued

Unless your doctor has instructed you to measure in a unit other than INR (i.e., %Quick or Seconds), you must confirm that the measured result is displayed as “INR” prior to using or reporting the result. Whenever the date and time settings are modified, repeat Steps 1 and 2.



NOTE

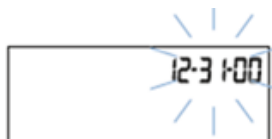
If the test result is displayed in %Quick (%Q) or Seconds (Sec), please follow the instructions below and on page 4 of this UMDc to change to INR test results.

Setting the Date and Time

To ensure your results are displayed in INR, you must first set up the date and time on your meter. This process will take you through Date and Time settings first.

1. Power the meter off.
2. Press the small blue **Set** button on the left side of your meter one time.

Once you press the **Set** button, the Date format flashes in the upper-right corner. You should see “12-31-00” flashing. *If these numbers are in a different order, press **M** until “12-31-00” is reached, and press the **Set** button.*



Now, the double-digit Year (00) should begin flashing.

3. Press the **M** button until the correct double-digit year displays. Once the year is correct, press the **Set** button to confirm the year and move to the month. The double-digit Month (12) should begin flashing.
4. Press the **M** button until the correct double-digit month is displayed. Press the **Set** button to confirm the month and move to the day. The double-digit Day (31) should begin flashing.
5. Press the **M** button until the double-digit day is correct and press the **Set** button to confirm the day and move to the time format. The Time format should begin flashing “12h” which represents a standard 12-hour format.
 - To accept this and move to the time setting, press the **Set** button.
 - To choose a 24-hour format, press the **M** button to see “24h” and press the **Set** button to move to the time setting. The Hour should begin flashing.
6. Press the **M** button until the correct AM or PM hour is reached.
7. Press the **Set** button to accept and move to the minutes. The Minutes should begin flashing.
8. Press the **M** button until the minutes are correct. Press the **Set** button to accept and move to the unit of measurement.

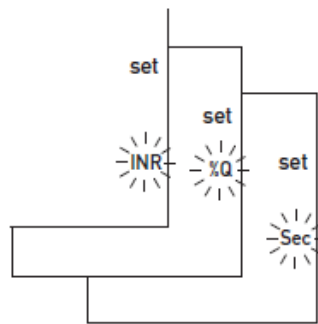
Patient Instructions, continued

Check the Measuring Unit for Your INR Test Result, continued

Now that the Date and Time are set on your meter, you will be prompted to set the INR display on your meter.

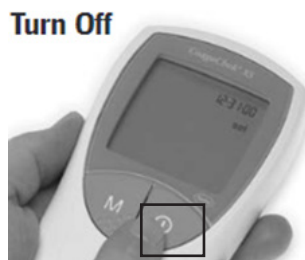
Setting Your Meter to Display INR

1. The Unit of Measurement should begin flashing. **Unless your doctor has instructed you to measure in a unit other than INR (i.e., %Quick or Seconds), it is very important your meter displays “INR” for its unit of measurement.**
 - If INR is flashing, press the **Set** button to accept.
 - If you see “%Q” or “Sec” flashing, press **M** until you reach “INR” and press the **Set** button to accept. This will ensure your test results display in the proper unit of measurement for correct reporting.



Always ensure “INR” is displayed when your test result appears, unless your doctor has specifically instructed you to measure in a unit other than INR (i.e., %Quick or Seconds).

2. The Beeper setting should begin flashing, which should read “On.” Press the **Set** button to accept. If “Off” is flashing, press the **M** button to change to “On,” and then press the **Set** button to accept.
3. Turn off the meter by pressing the power button, which looks like a circle with an “I” inside:



You have now ensured these important meter settings are correct!

If you need technical help, call the Roche Customer Support Center at 1-800-428-4674.

Actions to be Taken by Roche

Labeling changes will be made to the CoaguChek® XS PT Test 6 count (catalog number 04625374160) package insert and the CoaguChek XS User Manual for Patient Self Testing (literature number 04999045001) to:

- provide awareness of measuring unit settings
- ensure that the measuring unit result is set to INR
- provide instructions for resetting to INR units

Questions

Please contact the Roche Customer Support Center, Monday through Friday 7:00 a.m. to 11:00 p.m. EST, at 1-800-428-4674 if you have questions about the information contained in this UMDC.

This UMDC is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Reporting Program: Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form is available to fax or mail), or call FDA 1-800-FDA-1088.

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