

Urgent Field Safety Notice

SBN-CPS-2018-010

CPS / **cobas e** 411 analyzer
Version 1
Aug-2018

Change of pinch valve tubing exchange interval for the **cobas e** 411 analyzer

Product Name / GMMI	cobas e 411 analyzer (disk system) (GMMI 04775279001) cobas e 411 analyzer (rack system) (GMMI 04775201001)
Product Description	cobas e 411 analyzer for Immuno Chemistry
Production Identifier (Lot No./Serial No.)	Not applicable
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

A new pinch valve (3 ASSY) for the **cobas e** 411 analyzer (disk and rack system) was released in April 2018. With the release of pinch valve 3 ASSY the pinch valve tubing replacement was no longer part of the customer maintenance. The pinch valve tubing replacement interval with valve type 3 ASSY defined that if the instrument performs less than 50.000 tests per year the pinch valve tubing must be replaced during the yearly maintenance service by the Roche FSR (Field Service Representative). If the instrument performs more than 50.000 tests per year, the pinch valve tubing must be replaced every six months by the Roche FSR.

Due to an ongoing investigation resulting from an issue with the pinch valve 3 ASSY, we would like to inform you of a change in the interval for mandatory replacement of pinch valve tubing, regardless of the version of pinch valves (2 ASSY or 3 ASSY) that are installed on your **cobas e** 411 analyzer. Customers need to replace the pinch valve tubing after one month (when using sample reception mode) or after two months (when not using sample reception mode).

Please follow the mandatory replacement intervals (outlined above) of pinch valve tubing to avoid the risk of the following

- There is a possibility of too high results (only under certain conditions)
- The results could be out of the measuring range (only under certain conditions)
- An alarm is not triggered immediately when the problem is present (depending on the conditions)

Change of pinch valve tubing exchange interval for the cobas e 411 analyzer

Actions taken by Roche Diagnostics

The manufacturer Hitachi High Technologies Corporation has confirmed the issue for the reduced lifetime of the pinch valve tubing on the **cobas e 411** analyzer.

Hitachi High Technologies and Roche Diagnostics immediately started to investigate the root cause for the reduced life time of the pinch valve tubing. **We will update you if new information becomes available.**

Actions to be taken by the customer/user

The customer is advised to perform the following actions:

- Exchange the pinch valve tubing after one month when sample reception mode is used
- Exchange the pinch valve tubing after two months when sample reception mode is not used

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 or to any organization/individual where the potentially affected devices have been distributed/supplied.

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:

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.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com