

Field Safety Notice

SBN-CPS-2018-010

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

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

Product Name	cobas e 411 analyzer (disk system) (GMMI 04775279001) cobas e 411 analyzer (rack system) (GMMI 04775201001)
Product Description / GMMI	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,

With reference to SN-RPD-2017-431 Release of Pinch Valve 3 ASSY dated May 2018, we regret to inform that the on-board life time of the pinch tubing has to revert to the original claim.

An on-going monitoring of the 3 ASSY pinch valve showed damage to the inner side of the pinch valve tubing after 3-4 months of use. An investigation on the performance of pinch valve tubing with 3 ASSY pinch valve premature failure is underway. As a hardware alarm is not triggered for the failure, to avoid the risk of false high results (within and out of measuring ranges) reporting, we seek your support to ensure the mandatory pinch valve replacement at:

- After one (1) month (with sample reception mode ON)
- After two (2) months (with sample reception mode OFF).

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

Actions taken by Roche Diagnostics

Joint investigations by Hitachi High Technologies and Roche Diagnostics for the root cause of reduced life time of the pinch valve tubing with 3 ASSY pinch valve. **We will update you when 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 ON
- Exchange the pinch valve tubing after two months when sample reception mode is OFF

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 other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and thank you for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com