

Field Safety Notice

SBN-CPS-2018-002

CPS / Serum Work Area
Version 1
5-Mar-2018

cobas e 801 syringe plunger issue

Product Name	cobas® 8000 modular analyzer series cobas e 801 module
Affected Instrument Part GMMI / Part No	PLUNGER (798-3203)
Instrument/System Affected	cobas e 801 module (GMMI 07682913001) from serial numbers 1601-01 to 18E6-10
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

No affected customers in Singapore

Dear Valued Customer,

Description of Situation

Roche has received 3 complaints describing an issue with the syringe plunger on a **cobas e** 801 module PreWash (PW) syringe assembly. Investigations by the manufacturer have shown that this issue may also occur on the **cobas e** 801 module R1 or R2 reagent syringe assembly.

Depending on the affected syringe, R1, R2 or Prewash liquids will not be pipetted correctly, as follows:

1. If the Prewash syringe plunger is broken, the **cobas e** 801 module cannot detect it and no alarm is issued. In this instance, the prewash step required by most assays will not be performed and an impact on measurement results cannot be excluded. The "Important Information" section below outlines assays which are not affected by this issue. All other assays run on the **cobas e** 801 module may be affected.
2. If the R1 or R2 syringe plunger is broken, a system alarm "345-1 Warning Abnormal Low Signal" is generated and data alarm (<SigL) is flagged, consequently no measurement results will be generated.

Depending on how the seal pieces are assembled it is possible that the plunger is mounted in a tilted position which applies mechanical stress to the plunger. In the worst case scenario during the **cobas e** 801 initialization steps when the largest strokes happen, the plunger may crack leading to an impaired syringe function.

cobas e 801 syringe plunger issue

Important Information

If the described issue occurs with R1 or R2 syringe plunger:

1. A system alarm "345-1 Warning Abnormal Low Signal" is generated.
2. A data alarm (<SigL) is flagged.
3. No measurement results are generated.
4. Contact Roche Customer Support.

If the described issue occurs with the PW syringe plunger:

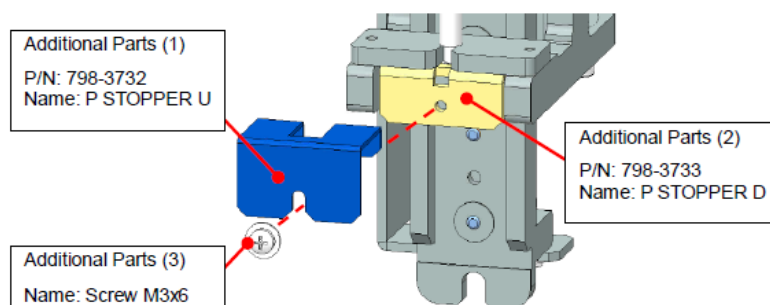
1. The following assays are not affected because they do not require the prewash step:

Elecsys Anti-CCP	Elecsys Anti-HAV IgM
Elecsys Anti-HBe	Elecsys Anti-TSHR
Elecsys CA 125 II	Elecsys CA 19-9
Elecsys CMV IgM	Elecsys FT4 II
Elecsys HBeAg	Elecsys hGH
Elecsys Rubella IgM	Elecsys Toxo IgM
Elecsys TSH	Elecsys Vitamin D II

2. All other **cobas e 801** assays require prewash steps and thus impact on measurement results cannot be excluded. If necessary repeat the measurement of concerned samples.
3. Follow the recommendations given in the section "Actions to be taken by the customer/user".

Actions taken by Roche Diagnostics

A mandatory installation of a syringe plunger guide for the R1, R2 and PW syringes is required for **cobas e 801** modules in the field, from serial numbers 1601-01 to 18E6-10, illustrated below:



The hardware modification kit (above seen additional parts) will be available early Q2/2018. It assures the correct positioning and movement of the referred syringe plungers and thus prevents the issue.

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Actions to be taken by the customer/user

Until the syringe plunger guide has been fitted to your **cobas e 801** module, you are requested to visually check the functionality of the PreWash syringe plunger by opening the instrument's front cover.

The maximum mechanical stress on PW syringe happens during its initialization steps. It is recommended to check the PW syringe right after the **cobas e 801** initialization and before starting with routine runs.

Refer to the attachments for additional details on how to identify a damaged PW syringe plunger:

- Att. 01_FSN_PreWash Plunger check during Pre-Operation
- Att. 02_FSN_PreWash Plunger check during System Prime

Important: If a damaged PW syringe plunger is identified, stop using the **cobas e 801** module and immediately contact Roche Customer Support. If necessary repeat the measurement of concerned samples.

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

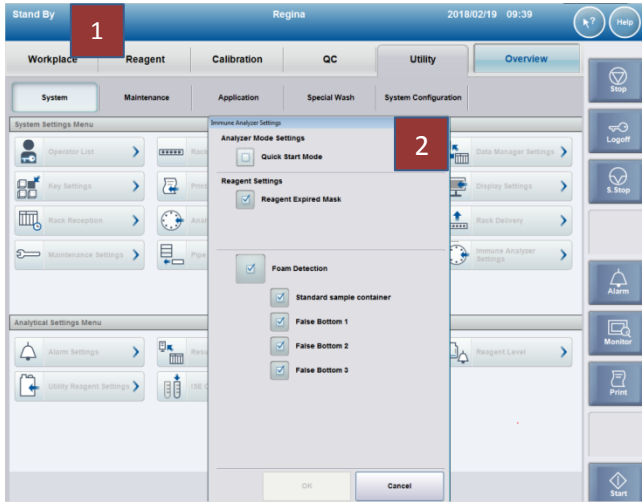
We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

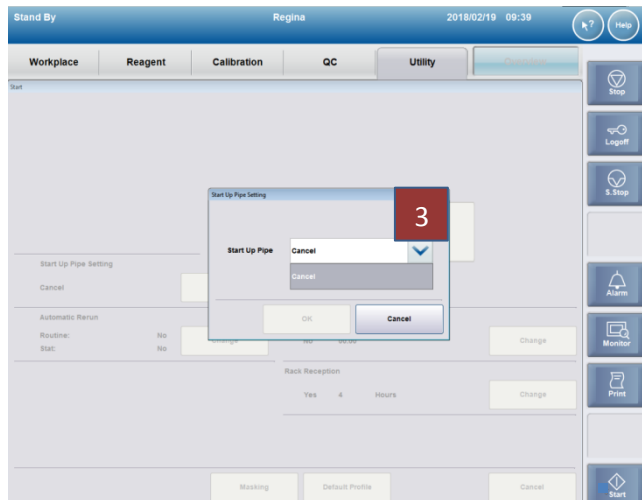
Email: sg.regulatory@roche.com

Procedure to check the Pre-wash Syringe Plunger function (during Pre-Operation process)

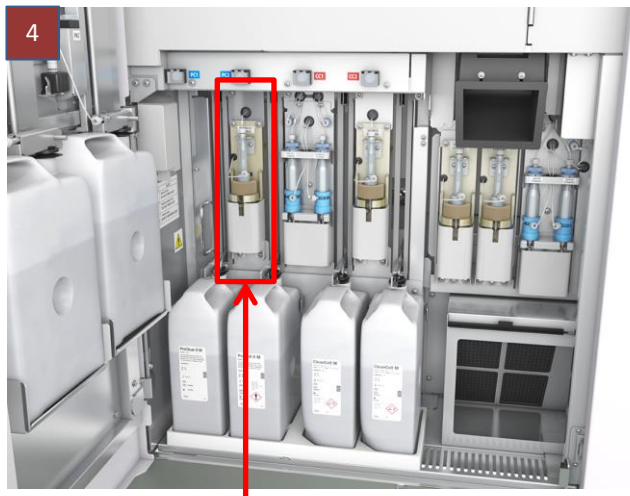


► Precondition

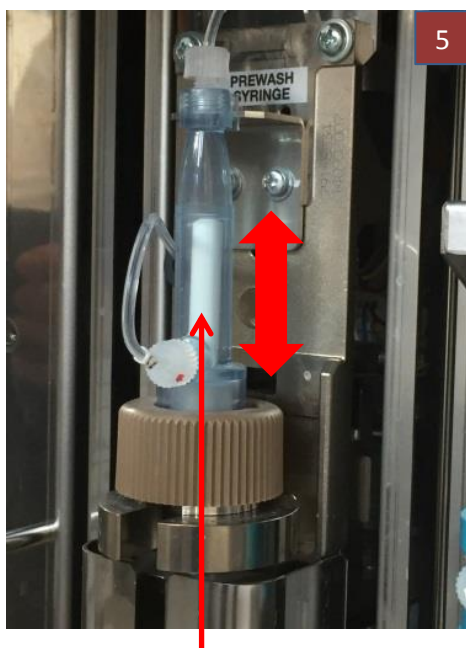
- 1 Instrument must be in **Standby** mode.
- 2 **Quick Start mode** is not selected.



- 3 **Start Up Pipe** is not used



Pre-wash syringe



Pre-wash Syringe Plunger

Check procedure

- 4 After Start of a routine run the instrument switches from **Standby** mode to **Preparation** mode.

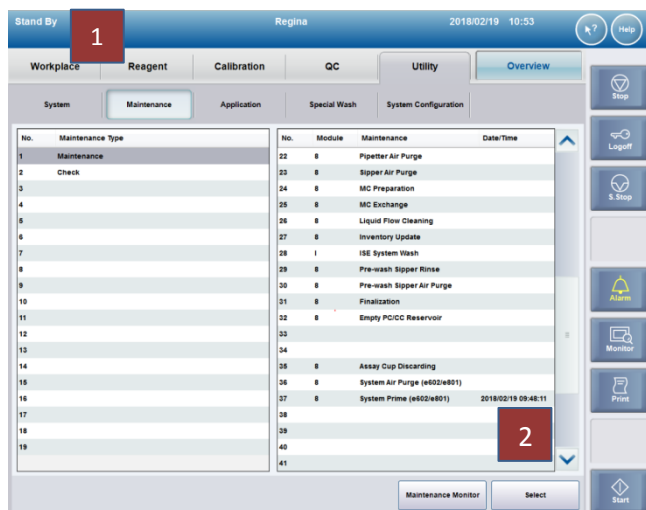
After approx. 50 seconds, the **cobas e 801** module carries out an Air Purge of the Pre-wash Sipper flow path.

- 5 To check the proper condition of the Pre-wash Syringe, open the **cobas e 801** module front cover. Visually verify that the white Plunger of the Pre-wash Syringe is moving up and down while the Pre-wash Unit is working. The stroke of the Plunger is not a performance relevant criterion.



If the Pre-wash Plunger is not moving, the **cobas e 801** module cannot be used. In this case call Roche Customer Support.

Procedure to check the Pre-wash Syringe Plunger function (using System Prime function)

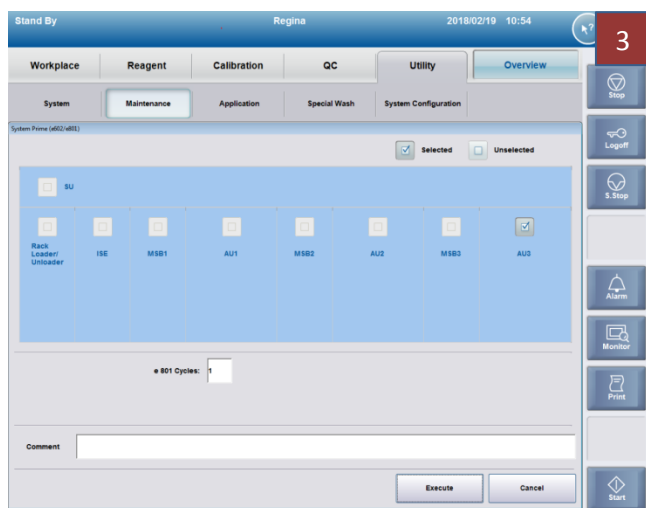


► Precondition

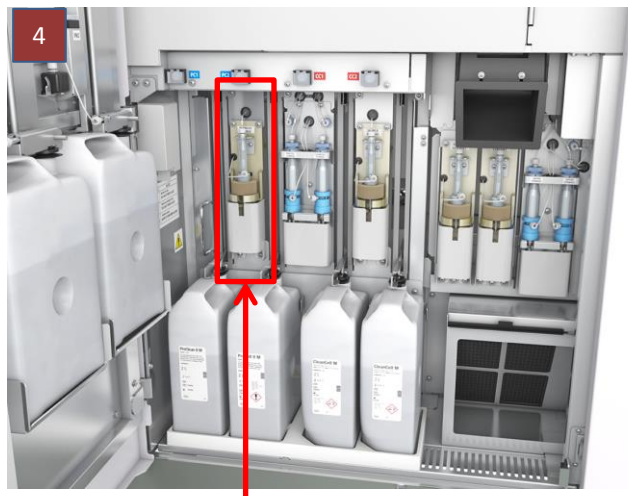
- 1 Instrument must be in **Standby** mode.

► Check procedure

- 2 Choose **Utility > Maintenance > Maintenance > 37 System Prime (e602/e801)**.



- 3 Select the **cobas e 801** module you want to check and press **Execute**.



Pre-wash syringe

- 4 After Start of the System Prime Maintenance function the instrument switches from **Standby** mode to **Maintenance** without rack mode.

After approx. 1 minute, the **cobas e 801** module carries out an Air Purge of the Pre-wash Sipper flow path.



Pre-wash Syringe Plunger

- 5 To check the proper condition of the Pre-wash Syringe, open the **cobas e 801** module front cover. Visually verify that the white Plunger of the Pre-wash Syringe is moving up and down while the Pre-wash Unit is working. The stroke of the Plunger is not a performance relevant criterion.



If the Pre-wash Plunger is not moving, the **cobas e 801** module can not be used. In this case call Roche Customer Support.