Urgent Field Safety Notice
SBN-CPS-2018-002

CPS / Serum Work Area
Version 3
xx-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)

Dear Valued Customer,

Description of Situation

Roche has received 4 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.

The hardware modification kit that solves this issue is already developed and available in our warehouse.

The installation of the kit requires few minutes, if the instrument is available in [Standby] mode. The kit assures the correct positioning and movement of the referred syringe plungers and thus prevents the issue.

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.

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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.

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
Elecsys BRAHMS PCT	

Table 1 – List of **cobas e** 801 non-prewash assays

2. The below listed **cobas e** 801 assays require prewash steps. The impact on measurement results by omitting prewash steps is assay-dependent. Studies were performed to investigate the impact of a missing pre-wash step on controls and samples.
Please find below the list of assays **with controls within range and samples within control range.**

TnT hs 18 min
TnT hs STAT
proBNP II 18 min
proBNP II STAT
Myoglobin 18 min
Myoglobin STAT
Digitoxin
hCG + ß
hCG STAT
Free ßhCG
FT3
Calcitonin
PTH
PTH STAT
PTH (1-84)

Table 2 – List of cobas e 801 assays with controls within range and samples within control range.

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3. The below listed **cobas e** 801 assays require prewash steps. The impact on measurement results by omitting prewash steps is assay-dependent. For the following assays, the impact on measurement results cannot be excluded.

Elecsys Digoxin	Elecsys FT4 II	Elecsys T3
Elecsys T4	Elecsys T-Uptake	Elecsys Anti-TPO
Elecsys Anti-Tg	Elecsys Tg II	Elecsys ACTH
Elecsys CK-MB (CK-MB/CK-MB STAT)	Elecsys Troponin I (TNI/TNI STAT)	Elecsys GDF-15
Elecsys AMH	Elecsys AMH Plus	Elecsys Cortisol II
Elecsys DHEA-S	Elecsys Estradiol III	Elecsys FSH
Elecsys Progesterone III	Elecsys Prolactin II	Elecsys LH
Elecsys Testosterone II	Elecsys C-Peptide	Elecsys SHBG
Elecsys PLGF	Elecsys sFLT-1	Elecsys Insulin
Elecsys CA 15-3 II	Elecsys CA 72-4	Elecsys AFP
Elecsys CYFRA 21-1	Elecsys free PSA	Elecsys CEA
Elecsys NSE	Elecsys ProGRP	Elecsys HE4
Elecsys S100	Elecsys SCC	Elecsys total PSA
Elecsys PAPP-A	Active B12	Elecsys Ferritin
Elecsys Folate (Folate/RBC Folate)	Elecsys Vitamin B12 II	Elecsys ß-CrossLaps
Elecsys N-MID Osteocalcin	Elecsys IgE II	Elecsys Rubella IgG
Elecsys total P1NP	Elecsys Cyclosporine	Elecsys Everolimus
Elecsys IL-6	Elecsys Tacrolimus	ISD Sample Pretreatment
Elecsys Sirolimus	Elecsys Anti-HBc II	Elecsys Anti-HBc IgM
Elecsys Anti-HAV	Elecsys Anti-HCV II	Elecsys HBsAg II
Elecsys Anti-HBs II	Elecsys Chagas	Elecsys HIV Duo
Elecsys HBsAg II quant II	Elecsys Syphilis	Elecsys CMV IgG
Elecsys HTLV-I/II	Elecsys HSV-1 IgG	Elecsys HSV-2 IgG
Elecsys CMV IgG Avidity	Elecsys Toxo IgG	Elecsys Syphilis
Elecsys Toxo IgG Avidity	Elecsys HIV Duo	Elecsys Anti-HCV II
Elecsys Anti-HBc II	Elecsys HBsAg II	Elecsys CMV IgG
Elecsys Chagas	Elecsys HTLV-I/II	

Table 3 – List of **cobas e** 801 prewash assays

4. Follow the recommendations given in the section **"Actions to be taken by the customer/user".**

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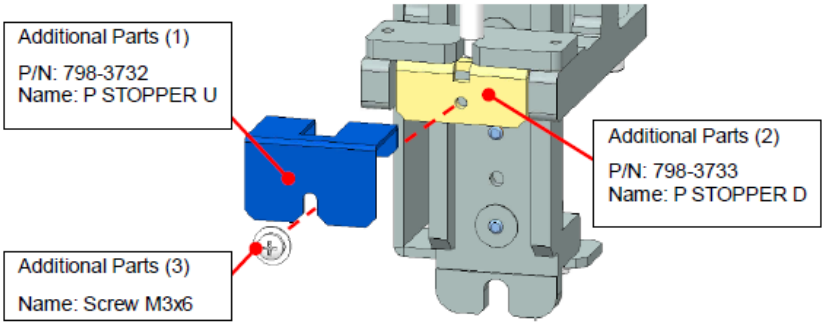
Actions taken by Roche Diagnostics

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:



Hardware modification kits (above seen additional parts) are already available in our warehouse.

The installation of the kit requires few minutes, if the instrument is available in [Standby] mode. The kit assures the correct positioning and movement of the referred syringe plungers and thus prevents the issue.

Actions to be taken by the customer/user

Roche Diagnostics' local representative will contact you to schedule the installation of the modification kit.

If it's not possible to have the above mentioned final solution (modification kit) in a timely manner, then please follow temporarily one of the below listed options (workarounds):

Option 1 (workaround):

This workaround (option 1) can be applied by the operators without support from a Roche field service representative.

Measure only assays that do not require prewash steps and assays which are not impacted by the missing prewash step.
The lists are found under "Important Information", Table 1 and Table 2.

Important:
The assays listed in **Table 3** under "Important Information" must **NOT** be measured until installation of the modification kit has been completed.
These assays have to be masked.

The procedure for test masking is available on **cobas**® 8000 Operator's Manual, under Operation > Order and results > Processing samples > Masking tests.

Option 2 (workaround):

This workaround (option 2) requires intervention from a Roche field service representative for the necessary configuration of the data manager: Consequences on the laboratory workflow will need to be considered.

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Visually inspect the functionality of the PreWash syringe plunger before manually releasing results to Host/LIS, till the final solution is applied.
The automatic data transfer function of patient sample results on data manager needs to be disabled, so patient results measured on **cobas e** 801 module (prewash assays only) will not be automatically transferred to Host/LIS. Instead, these measurement results must be manually released to Host/LIS after visually checking the functionality of the PW syringe plunger.

Option 2 - Procedure:

1. Define the time interval to visually inspect the PreWash syringe plunger and manually validate results (for prewash assays) on data manager to be sent to Host/LIS.
2. Start sample processing and after the above defined time interval stop the operation with the [S.Stop] button and wait till the system goes to [Standby] mode.
3. Visually check the PreWash syringe plunger movement, according to the attachment: "Att. 01_FSN_PreWash Plunger check during System Prime"
4. If the PreWash syringe plunger is visually working as expected, manually validate the transfer of patient results measured on **cobas e** 801 from data manager to Host/LIS. During the manual validation of patient results, it is recommended that the system is kept in [Standby] mode and no new samples are loaded.
5. Repeat Step 2 – 4 until the end of routine operation.

Important: If a damaged PreWash syringe plunger is identified (see the above procedure, step 3), stop using the **cobas e** 801 module and immediately contact Roche Customer Support. In addition, do not validate the measured results and repeat the measurement of concerned samples.

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. (If appropriate)

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate)

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

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: 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.

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Best regards,

Contact Details

To be completed locally:
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