

Urgent Field Safety Notice

SBN-CPS-2019-015



CPS / Serum Work Area Systems

Version 1

July-2019

Potential malfunction in high pressure solenoid valves

System	Material Number
cobas c 311 analyzer	04826876001
cobas c 501 module	04745914001
cobas c 502 module	05964067001
cobas c 513 analyzer	07649142001
cobas c 701 module	05641489001
cobas c 702 module	06473245001
cobas pro ISE analytical unit	08464537001
cobas 8000 ISE module 900	05641497001
cobas 8000 ISE module 1800	05964075001
cobas e 601 module	04745922001
cobas e 602 module	05990378001
cobas e 801 module	07682913001
cobas e 801 analytical unit	08454345001
cobas c 503 analytical unit	08463662001

Production Identifier (Product name/Product code)	n/a
---	-----

SW Version	n/a
-------------------	-----

Type of Action	Field Safety Corrective Action (FSCA)
-----------------------	---------------------------------------

Please note that this FSN is relevant only to specific serial numbers which are impacted and those customers affected will be contacted immediately by Roche local organization.

Dear Valued Customer,

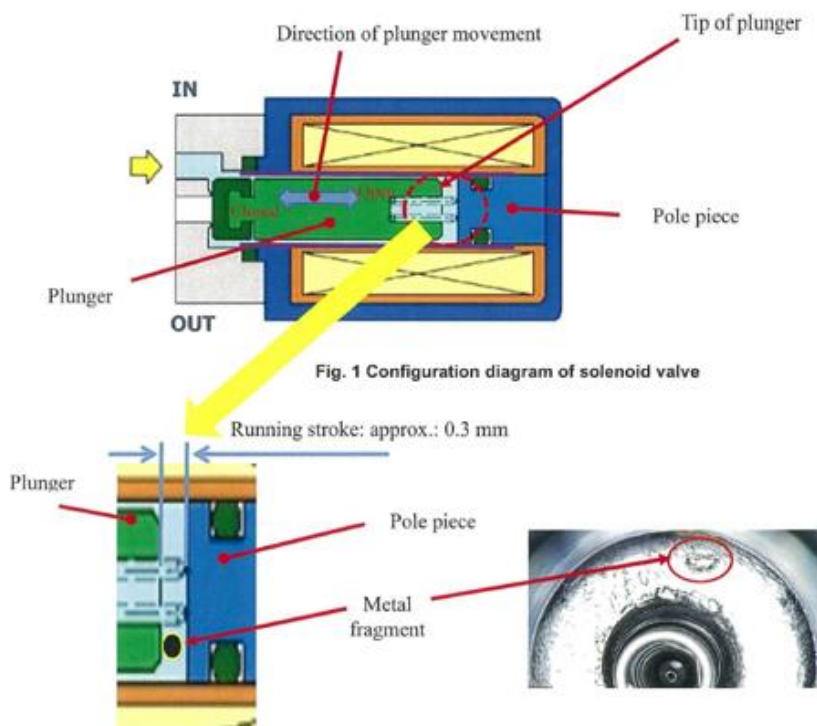
We were recently informed by the manufacturer Hitachi High Technologies (HHT) about a quality issue with high pressure solenoid valves, the issue had been identified in the Hitachi product "Labospect". Nevertheless, **cobas 8000** modular analyzer series (**cobas 8000** ISE module, **cobas c** 701 module, **cobas c** 702 module, **cobas c** 502 module, **cobas e** 602 module, **cobas e** 801 module, **cobas e** 801 analytical unit), **cobas 6000** analyzer series (**cobas c** 501 module, **cobas e** 601 module), **cobas pro** integrated solutions (**cobas pro** ISE analytical unit, **cobas c** 503 analytical unit), **cobas c** 513 analyzer and **cobas c** 311 analyzer are also potentially affected as those products use the same high pressure solenoid valves.

Potential malfunction in high pressure solenoid valves



The manufacturer Hitachi High Technologies (HHT) has identified the root cause and the corrective actions are clearly defined and are in progress.

The root cause is related to metallic fragments peeling from the plunger in the solenoid valve. This metal fragment may prevent proper plunger movement and accordingly lead to potential malfunctioning of the solenoid valve opening/closing functionality (solenoid valve totally open and solenoid totally closed mode).



Note: The high pressure solenoid valves produced between January 2019 and May 2019 are potentially affected. Those valves have been used in the production of systems as well as spare parts.

The manufacturer has identified all potentially affected instruments and where these have been shipped. In the time period from January 2019 to date Roche has shipped out a small number of potentially affected solenoid valves as spare parts; again, it has been identified where these have been shipped.

With the affected solenoid valves, the malfunction cannot always be detected and an impact on patient results cannot be excluded. Erroneous results without data flag or system alarm cannot be excluded.

Potential malfunction in high pressure solenoid valves



Actions taken by Roche Diagnostics

1. For the small number of affected units (encompassing **cobas e 601** modules, **cobas 8000** ISE modules, **cobas c 701** modules, **cobas pro** ISE analytical units) which have been already installed and may be in routine use, the affiliate's local field service representatives will execute the necessary valve modification with the highest priority.
2. For the systems where the potentially affected spare part valves have been exchanged during repair visits done in the period from January 2019 to date (small number of affected spare part valves were shipped out during that time period), the affiliate's local field service representatives will execute the necessary modification with the highest priority.
3. The stocks (in the global warehouse as well as in the local affiliates) of the potentially affected serial numbers have been blocked until the modification of the affected solenoid valves has been carried out (the modification will be applied by the manufacturer Hitachi High Technologies (HHT) or by the affiliate's local field service representatives as appropriate, depending on stock location).
4. The spare parts stocks (in the global warehouse as well as in the local affiliates) of the potentially affected valves have been blocked and a replacement process with unaffected valves is ongoing.

Actions to be taken by the customer/user

Please note that the actions below are only relevant to specific serial numbers which are impacted and those customers affected will be contacted immediately by Roche local organization.

1. cobas 8000 ISE modules, cobas c 701 modules and cobas pro ISE analytical unit:

Your local Roche organization will contact you directly if one of the affected instruments has been installed within your laboratory or network.

For the affected cobas 8000 ISE modules, cobas c 701 modules and cobas pro ISE analytical units please stop using those units until the necessary valve modification is implemented.

2. cobas e 601 module:

Your local Roche organization will contact you directly if one of the affected instruments has been installed within your laboratory or network.

For the affected cobas e 601 modules, please follow the attached procedure until the necessary valve modification has been completed.

3. For systems potentially affected by solenoid valve spare part replacement:

If your system is impacted, you will be contacted directly by your local Roche organization and the affected valve will be replaced with the highest priority.

Potential malfunction in high pressure solenoid valves



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 where the devices have been distributed/supplied. (If appropriate).

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:

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.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

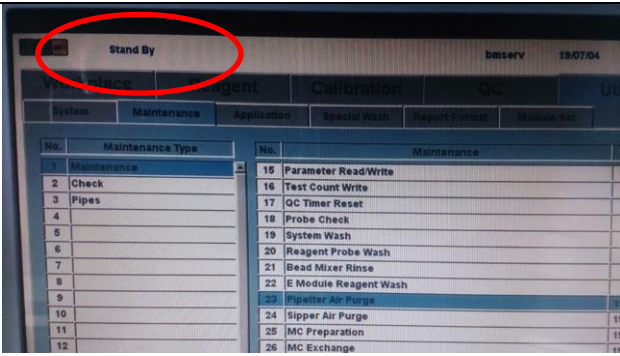

Customer Solenoid Valve Check Procedure for cobas e 601 module

In order to check the reliable function of the high pressure solenoid valves on the **cobas e 601** module, please see below the appropriate procedure. This should be done along with your usual QC-procedures (e.g. once per shift) and results should only be released once checks before and after have been performed and passed.

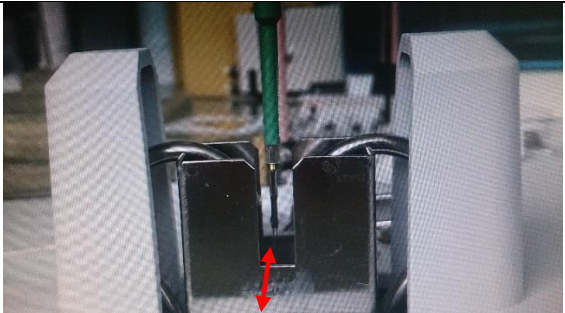
Safety: please read these instructions carefully before executing the procedures, operating a **cobas** analytical unit with open cover can be a risk for personal safety when moving parts are touched.

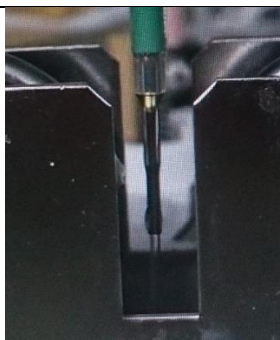
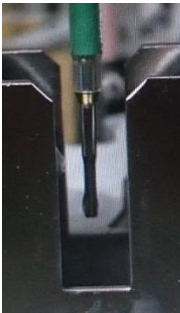
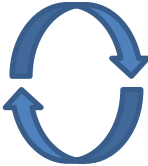
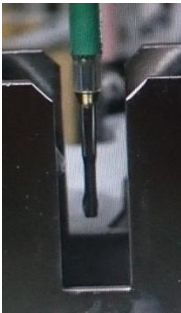
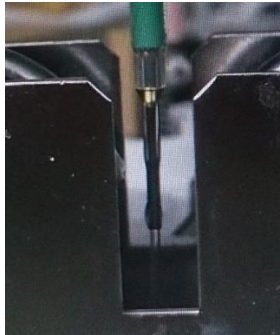

Step 1	Activate stand-by mode of selected analytical unit cobas e 601 , open cover and locate both wash stations for reagent probe and for pre-wash sipper probe	(for details please refer to appendix 1)
↓		
Step 2	Check <u>reagent probe washing</u>	(for details please refer to appendix 2)
↓		
Step 3	Check <u>pre-wash sipper probe washing</u>	(for details please refer to appendix 3)
↓		
Step 4	If step 2 and 3 are ok then the analytical unit is ok in terms of solenoid valve (SV2 & SV30) functionality.	

Appendix 1: stand-by mode, open cover and how to locate both wash stations for reagent probe and for pre-wash sipper probe:

	 <p>Pre-wash sipper probe wash station</p> <p>Reagent probe wash station</p>
Stand-by mode	Wash stations as seen with open cover


Appendix 2: how to select service function for reagent probe inner wash and how to see malfunction visually:

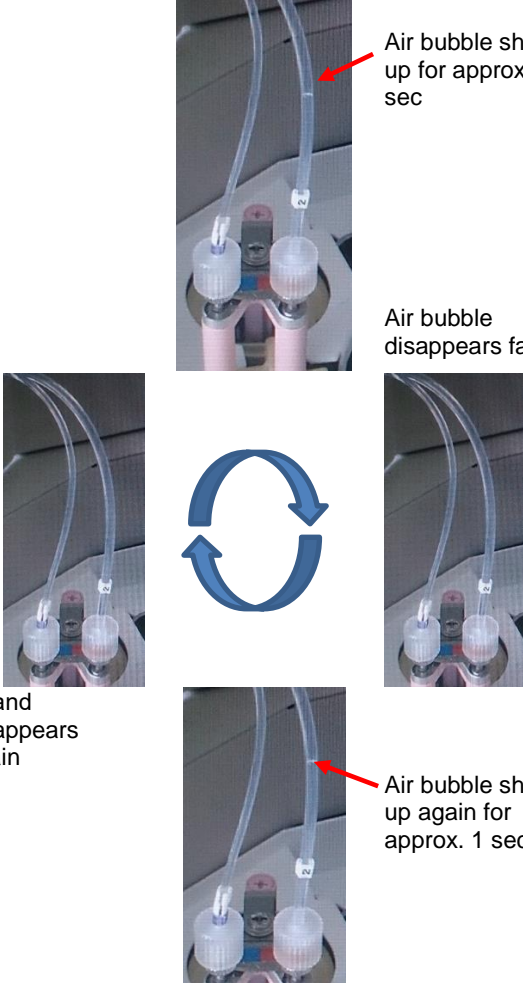

<p>In stand-by mode of analytical unit Select UTILITY → MAINTENANCE → PIPETTOR AIR PURGE → SELECT → CYCLES 3 → EXECUTE</p>	 <p>jet of liquid leaving probe</p>
--	---

 <p>constant jet of liquid for approx. 1 sec</p>  <p>no liquid for approx. 1 sec</p>   <p>no liquid for approx. 1 sec</p>  <p>constant jet of liquid for approx. 1 sec</p>	 <p>Foam at end of reagent probe</p>
--	--

<p>Ok: a regular repeated jet of liquid is ejected from reagent needle into wash station for approx. 1 sec, then a pause with no liquid for approx. 1sec, then cycle starts from the beginning</p>	<p>Not ok:</p> <ul style="list-style-type: none"> - no jet of liquid, - air bubbles, foam - constant, not interrupted flow coming out of reagent probe
--	---

Appendix 3: how to select service function for sipper probe inner wash and how to see malfunction visually:

<p>In stand-by mode of analytical unit Select UTILITY → MAINTENANCE → PRE-WASH SIPPER AIR PURGE → SELECT → CYCLES 3 → EXECUTE</p>	 <p>air bubbles are observed frequently</p>
---	---

 <p>Air bubble shows up for approx. 1 sec</p> <p>Air bubble disappears fast:</p> <p>... and disappears again</p> <p>Air bubble shows up again for approx. 1 sec</p>	 <p>Irregular, large air bubble in right tubing of pre-wash sipper probes</p>
<p>Ok: pre-wash sipper probe washing is checked by observation of the tubings connected to both probes: the right tubing must show a small air bubble popping up regularly from the probe, i.e. appearing and disappearing on a regular time scale</p>	<p>Not ok:</p> <ul style="list-style-type: none"> - large air bubble(s) in tubing, - irregular air bubbles, foam, - no air bubble at all.