

# Field Safety Notice

## SBN-CPS-2019-015

CPS / Serum Work Area Systems  
Version 1  
24-Jul-19

## 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     |

|                    |                                       |
|--------------------|---------------------------------------|
| Product Identifier | Not applicable                        |
| SW Version         | Not applicable                        |
| Type of Action     | Field Safety Corrective Action (FSCA) |

**Please note that this FSN is relevant only to specific serial numbers. Affected instruments are not available in Singapore.**

Dear Valued Customer,

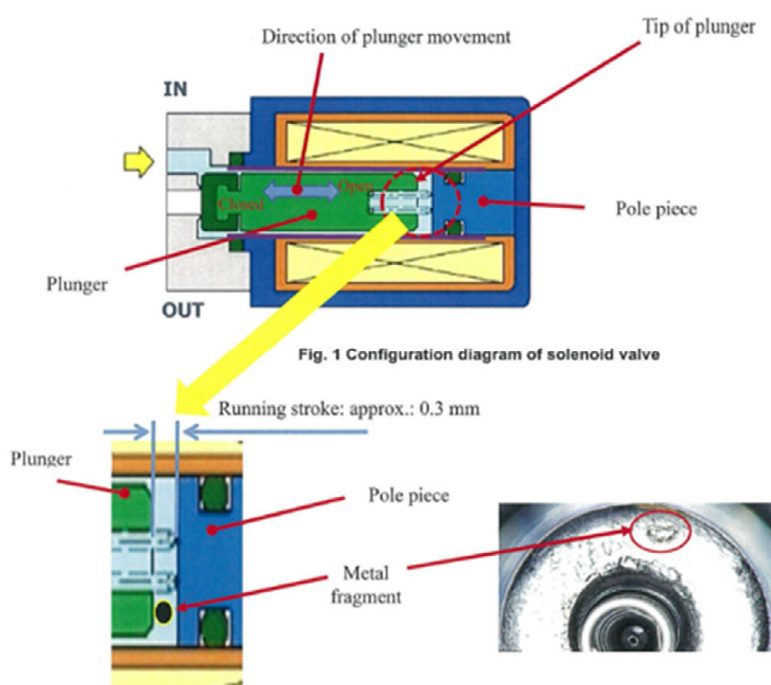
We were recently informed by the manufacturer Hitachi High Technologies (HHT) about a quality issue with high pressure solenoid valves, the issue had been identified in the Hitachi product "Labospect". Nevertheless, cobas 8000 modular analyzer series (cobas 8000 ISE module, cobas c 701 module, cobas 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

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the same 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.

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## 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

### 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.

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## 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](mailto:sg.regulatory@roche.com)