

# Field Safety Notice

## SBN-SIS-2019-002

SIS / Laboratory Integration  
Version 1  
20-Mar-2019

### Loose screws on the Tray Input Flap of the cobas p 501 /p 701 post-analytical units

<b>Product Name</b>	cobas p 501 / 701 post-analytical units
<b>Product Description</b>	Instrument stores primary and secondary sample tubes
<b>GMMI / Part No</b>	05158494001, 05349966001
<b>Device Identifier</b>	
<b>Production Identifier (Lot No./Serial No.)</b>	Serial No. cobas p 501: [REDACTED] Serial No. cobas p 701: [REDACTED] Serial No. cobas p 701: [REDACTED]
	<div style="border: 1px solid red; padding: 5px; color: red;">             cobas p 501: No affected serial number in Singapore              cobas p 701: No supply in Singapore           </div>
<b>SW Version</b>	Not applicable
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

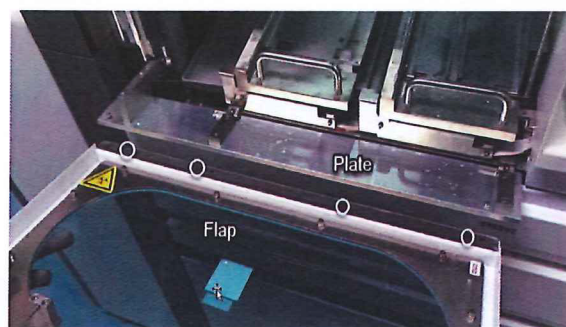
### Description of Situation

The Tray Input Flap on the cobas p 501 and cobas p 701 post-analytical units has the potential to become unsecured from the instrument.

The Tray Input Flap screws can become loose on the cobas p 501 or p 701 post-analytical units resulting in the potential detachment from the instrument.

Visual inspection of the Tray Input Flap, plate and screws were performed. As demonstrated in the pictures below, the flap was no longer attached to the instrument and the 4 M3 threads on the Tray Input Flap were worn out resulting in the screws not working as intended.

## Loose screws on the Tray Input Flap of the cobas p 501 /p 701 post-analytical units



This design of Tray Input Flap was installed on all instruments with the following Serial Numbers:

cobas p 501, Serial Number [REDACTED]

cobas p 701, Serial Number [REDACTED]

cobas p 701, Serial Number [REDACTED]

Instruments with Serial Numbers [REDACTED] for the cobas p 501 and [REDACTED] for the cobas p 701 are not affected as they have a newer design of Tray Input Flaps.

### Actions taken by Roche Diagnostics

The Tray Input Flaps on instruments with the above listed serial numbers must be replaced by Roche Diagnostics with the current design of the tray input flaps with an estimated completion date of 30-September-2019.

### Actions to be taken by the customer/user

Prior to the replacement tray input flaps being installed, always inspect tray input flap to ensure the tray input flap is securely attached to the instrument. If the flap is not fastened securely or becomes loose prior to the tray input flap being replaced, please contact Roche Diagnostics to repair the instrument.

# Loose screws on the Tray Input Flap of the cobas p 501 /p 701 post-analytical units

## 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 apologise 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)