

Urgent Field Safety Notice

SBN-CPS-2019-013

CPS Lab Coagulation
Version 1
June- 2019

cobas t 511/ t 711: Liquid waste overflow

Product Name/Description	cobas t 511 coagulation analyzer cobas t 711 coagulation analyzer
GMMI / Part No	06356460001
Device Identifier	06355790001
Production Identifier (Lot No./Serial No.)	cobas t 511 SN 1001-1061 SN 1064-1067 SN 1069-1073 SN 1081 cobas t 711: SN 1001-1065 SN 1069-1074 SN 1075-1078 SN 1080+1081 SN 1084
SW Version	All
Type of Action	Field Safety Notification

Dear Valued Customer,

Roche Diagnostics regrets to inform you of reported cases affecting the **cobas t 511** and **cobas t 711** coagulation analyzers.

Description of Situation

The **cobas t 511** and **cobas t 711** coagulation analyzers have a waste management system that is based on weight sensors, which trigger the switch between the two waste containers and the respective warnings to the user. The instruments of the affected serial range have a revision of weight sensor built in that may fail sporadically. As a result, waste overflow may happen into the black drip pan or onto the floor.

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Waste container



Black drip pan

In such a case, the respective cleaning actions must be performed by the operator or Roche service engineer using appropriate protective equipment as indicated in the User Assistance/Operator Manual. In the event the overflow exceeds the volume in the black drip pan, a defect of the load cell (due to liquid) is possible. Due to reserve volume in the container itself, it may also be that no overflow occurs but only a very well filled container.

Actions taken by Roche Diagnostics

Corrective Action:

- A Roche Field Service Engineer will be in contact to replace all weight sensors of the affected systems
- The required parts and repair is free of charge.

Actions to be taken by the customer/user

Workaround:

Until the replacements have taken place, start the routine with two empty waste containers as indicated in User Assistance/Operator Manual. From that point on, it is recommended that the waste containers should be checked every 1.5 hours on a **cobas t 711** instrument and every 3 hours on a **cobas t 511** instrument preventively to avoid the issue. These times are based on a maximum throughput estimates.

If the issue has occurred prior to the replacement, contact the local Roche Service Representative and request the immediate replacement of the weight sensors. Once the weight sensor is replaced by Roche the workaround is no longer required.

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.

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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.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com