

Urgent Field Safety Notice

SBN-CPS-2018-020

CPS / coagulation **cobas t 511** and **cobas t 711**
Version 1
Dec-2018

cobas t 511 and t 711 - Clean Probe Assembly

Product Names	cobas t 511 coagulation analyzer cobas t 711 coagulation analyzer
GMMI / Part No Device Identifiers	GMMI 06356460001 (cobas t 511) GMMI 06355790001 (cobas t 711)
Production Identifier (Lot No./Serial No.)	N/A
SW Version	All SW versions up to / including 2.0.1
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

It has come to our attention that the maintenance procedure for cleaning the sample probe as described and guided by the instrument SW is inadequate; consequently, there is potential for operator injury when following this procedure.

The software guided maintenance action includes the cleaning steps for cleaning the probes, drip trays and tube holder. Cleaning the tube holder requires the removal and reattachment of the tube holder after cleaning (refer to step 8 (**cobas t 511**) and step 9 (**cobas t 711**) of the maintenance instructions of the system software). It is this part of the instructions which needs revision.

Attention: the down holder does not necessarily lock in the maintenance position. If too much force is applied during reattaching the tube holder, the down holder can unexpectedly move upwards and release the sample probe. During this step there is the potential for operator injury by the sample probe.

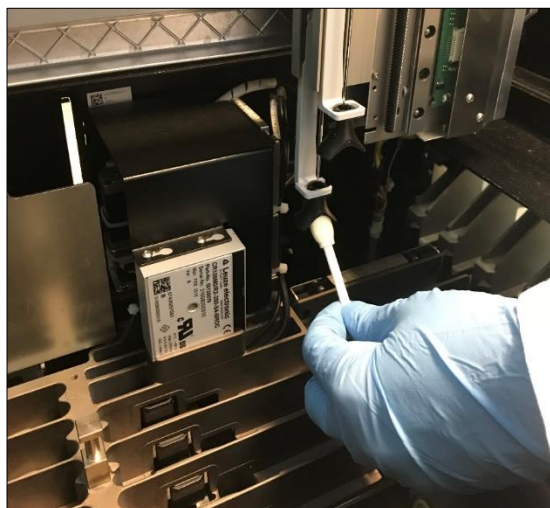
As a solution the maintenance procedure has been revised. The last 3 steps for removing, cleaning and reattaching of the tube holders are replaced by one new step. Instead of removing the tube holders the cleaning will be performed without removal by using special lint-free swabs. Refer to the following tables describing the procedures for each analyzer and the picture:

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cobas t 511		
Step	Old procedure	New procedure
1	Open Main Cover	Open Main Cover
2	Remove drip trays	Remove drip trays
3	Clean probes	Clean probes
4	Clean drip trays	Clean drip trays
5	Reattach drip trays	Reattach drip trays
6	Remove tube holders	Moisten the cleaning swab with disinfectant, and clean the inside of the tube holder
7	Clean tube holder	
8	Reattach tube holder	

cobas t 711		
Step	Old procedure	New procedure
1	Open Main Cover	Open Main Cover
2	Remove drip trays	Remove drip trays
3	Clean probes	Clean probes
4	Clean drip trays	Clean drip trays
5	Reattach drip trays	Reattach drip trays
6	Move reagent transfer arm	Move reagent transfer arm
7	Remove tube holders	Moisten the cleaning swab with disinfectant, and clean the inside of the tube holder
8	Clean tube holder	
9	Reattach tube holder	

The following picture will show the cleaning of the sample probe by using the lint-free swabs:



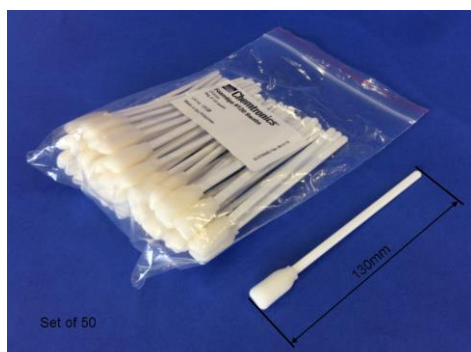
Be aware: other kind of swabs should not be used, due to the risk of lints.



A pack of 50 of these swabs are part of the **cobas t 511** and **711** startup kits and more can be ordered from Roche

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(Material. no. 08288267001). Chemtronics® Foamtips #120 Swabs



This updated procedure will mitigate the risk of injury if performed as instructed.

The exact description of the procedures please refer to attachments:

1. Procedure **cobas t 511**
2. Procedure **cobas t 711**

Actions taken by Roche Diagnostics

1. The updated software version 2.0.2 will include the change in the software guided maintenance action. The new software version 2.0.2 is anticipated to be released in April 2019.
2. Necessary changes in the User Assistance/Operator Manual will be provided at the same time.

Actions to be taken by the customer/user

This revised maintenance actions are described in the attachments and have to be followed with immediate effect until the software version 2.0.2 was installed.

Communication of this Field Safety Notice (if applicable)

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.

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.

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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.

Kind regards,

Contact Details

Attachments:

1. Procedure **cobas t 511**
2. Procedure **cobas t 711**