

Field Safety Notice

SBN-CPS-2018-020

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

t 711 - Clean Probe Assembly

Product Name	cobas t 711 coagulation analyzer	
GMMI / Part No	GMMI 06355790001 (cobas t 711)	No affected customers in SG
Device Identifiers	<i>Note: There may be other affected identifiers that are affected globally. Please contact the product owner if the device is obtained from an overseas dealer</i>	
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 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 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	

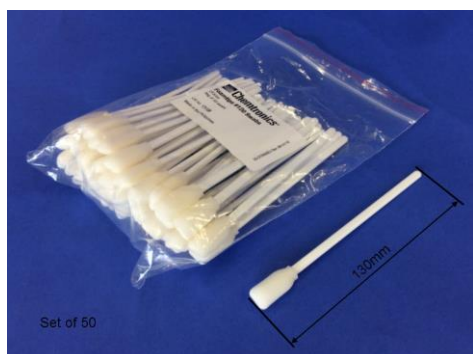
The following picture will show the cleaning of the sample probe by using the lint-free swabs:



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 711** startup kits and more can be ordered from Roche (Material. no. 08288267001). Chemtronics® Foamtips #120 Swabs



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

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The exact descriptions of the procedures please refer to attachment:

1. 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

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

Attachments:

1. Procedure **cobas t 711**

Instruction clean probe assembly cobas t 711

Difference between old and new procedure

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	

WARNING

Contact with sample probes

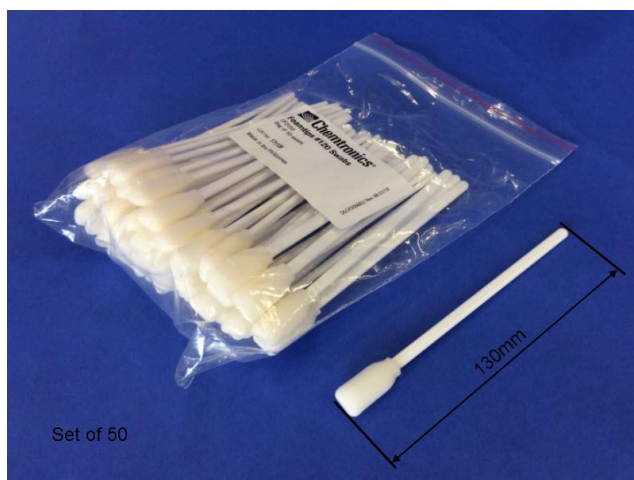
Contact with sample probes may result in injury and infection.

- ▶ Avoid touching the end of the sample probes
- ▶ Avoid contacting the sample probes during maintenance
- ▶ Wear appropriate personal protective equipment.
Take extra care when working with lab gloves. They can easily be pierced or cut, leading to infection.

Parts Required

SWABS LINT-FREE Mat#08288267001 (Set of 50), Chemtronics® Foamtips #120 Swabs

Note: This material is also part of the startup kit of the **cobas t 711**



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Instructions Maintenance Action 'Clean probe assembly'

As usual start 'Clean probe assembly' maintenance action in the software, then follow steps as described below also in the software wizard.

1. Open main cover and click *Next Step*



Open the main cover.

WARNING: Risk of infection due to contact with contaminated surfaces. Wear lab gloves.

2. Remove drip tray and click *Next Step*

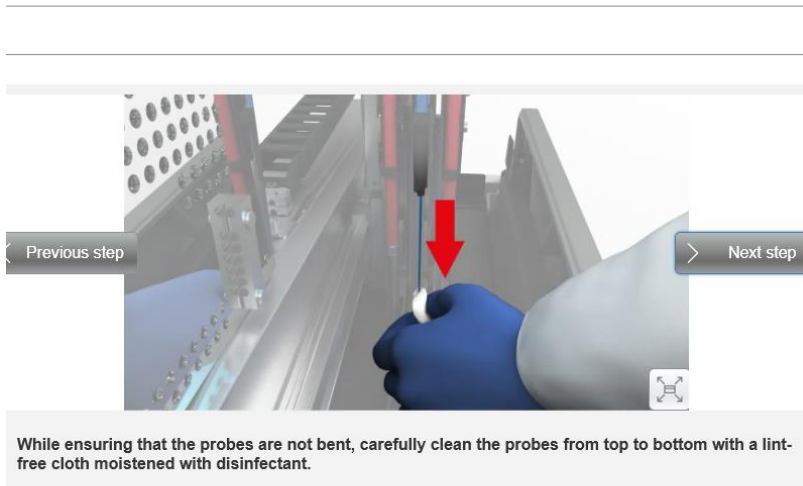


While ensuring that the probes are not bent, carefully remove the drip trays in a downward motion beginning with R1.

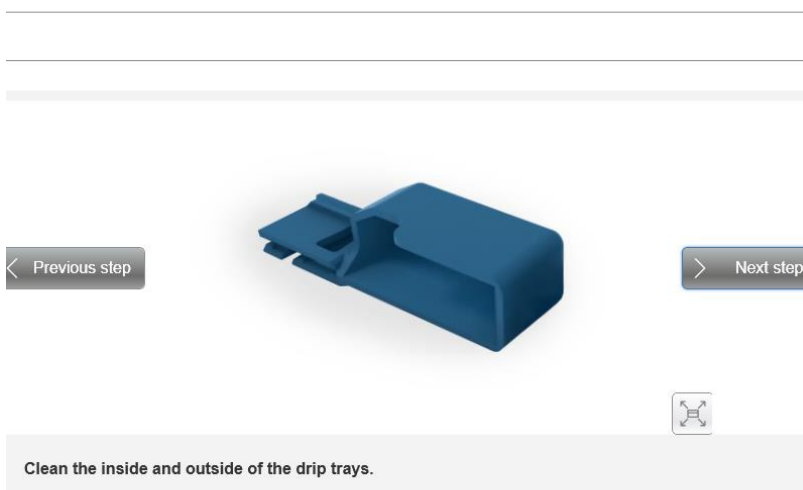
WARNING: Risk of personal injury and infection. Use caution around the reagent probes. Wear lab gloves.

Instruction clean probe assembly cobas t 711

3. Clean probes and click *Next Step*

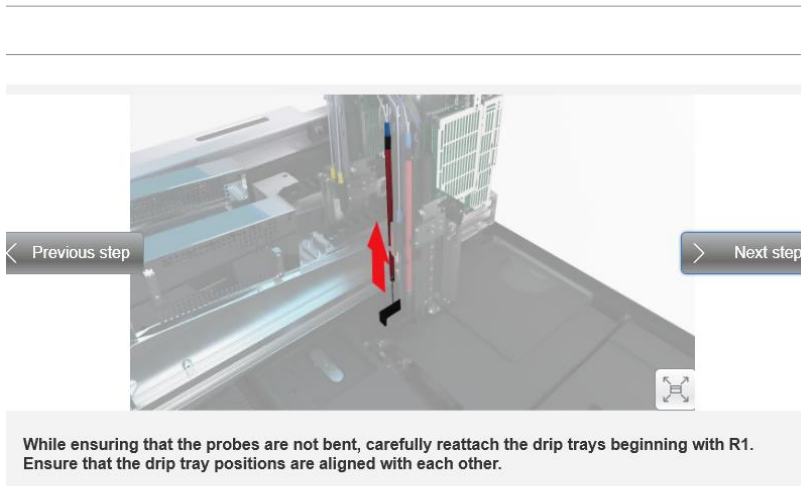


4. Clean drip trays and click *Next Step*

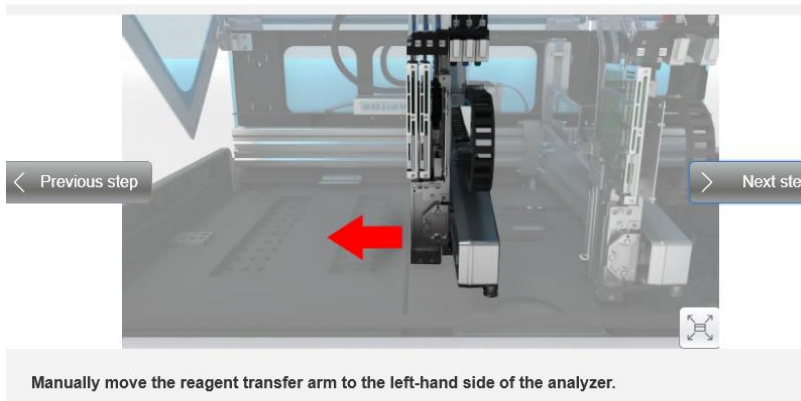


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5. Reattach drip trays and click *Next Step*



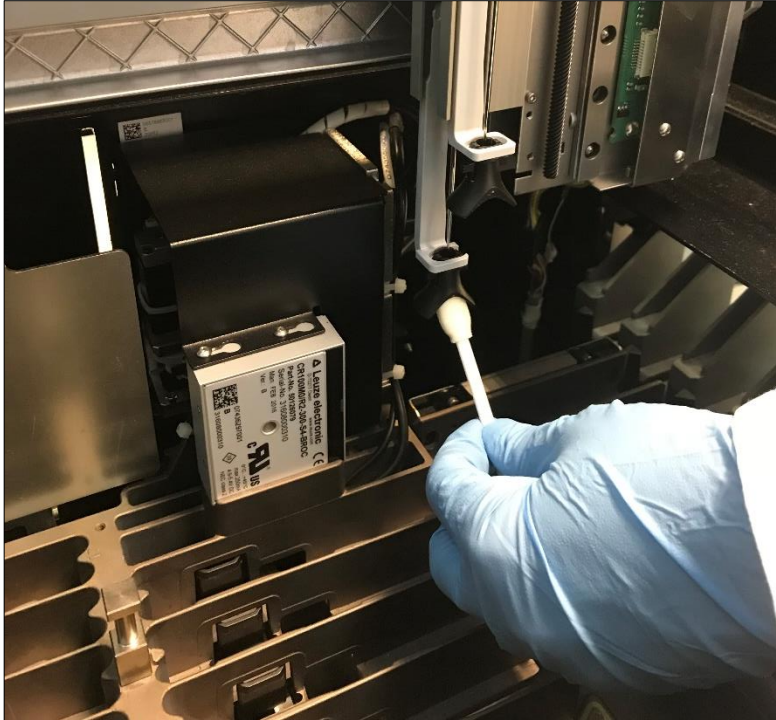
6. Move reagent transfer arm and click *Next Step*



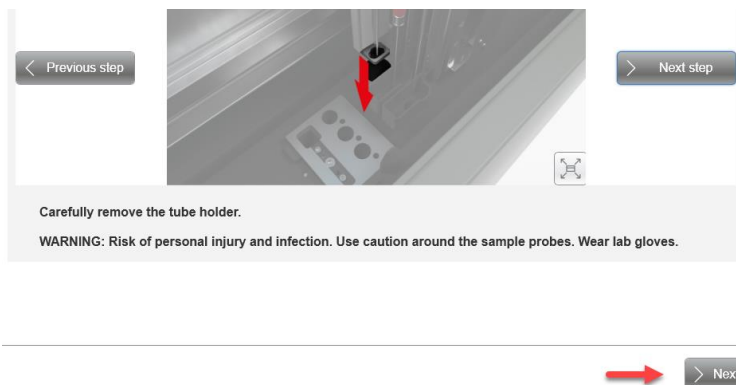
Important: Do not continue to remove tube holder, continue now with step 7 below.

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7. Moisten the cleaning swab with disinfectant, and clean the inside of the tube holder.



Now the maintenance tasks are completed, to finish the maintenance action, click on *Next*.



Follow the remaining instructions of the maintenance action.