

Field Safety Notice

SBN-CPS-2016-013

CPS / Serum Work Area
Version 1
12 September 2016

New mandatory cleaning procedure for rack trays

Product Name	Refer to Attachment 1
GMMI / Part No	Refer to Attachment 1
Device Identifier	
Instrument/System Affected	Refer to Attachment 1
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We would like to inform you about an update of the cleaning procedure for rack trays. It is mandatory to follow this cleaning procedure which contains instructions for safe handling of the parts to avoid the risk of injury (edges may cause cuts of skin during rack tray cleaning when fingers come in contact with rack tray edges and fingers move quickly along the edges of rack tray). We apologize for any inconvenience this may cause and hope for your understanding.

This is applicable to all Instruments/Systems using rack trays.

Please find attached the detailed description of the cleaning procedure.

Actions taken by Roche Diagnostics

Recently we have become aware of in total 5 cases of injuries (cut of skin) caused by edges on rack trays during cleaning. The following action was taken:

- Creation of a consolidated cleaning procedure to be included into user documentation of all Instruments/Systems using rack trays

New mandatory cleaning procedure for rack trays

Actions to be taken by the customer/user

It is mandatory to follow the cleaning instructions for rack trays, provided with attachment 2 to this Field Safety Notice.

Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com

Attachment 1 to SBN-CPS-2016-013

Rack Trays	Material Number
RACK TRAY ASSY	03024563001
RACK TRAY	03025730001
RACK TRAY	03378900001
RACK TRAY	03723194001
RACK TRAY	04679431001
New HHT 75 Position Tray	04917057001
Rack Tray, 75 pos, collapsible, PVT	05099986001
RACK TRAY ASSY	05288495001
Tray collapsible handle f. 5 HHT racks	05640423001
Tray collapsible handle f. 8 HHT racks	05640431001
Rack Tray 714-3092	06601855001
RACK TRAY 747-100 (SHORT)	11226517001
RACK TRAY (LONG) f.RSD 800/RSD800A	11561952001
TRAY, SAMPLE RACK 5	11807340001
75 pos. Roche/Hitachi Racktray*IM	11906984001
RACK TRAY, 75 POS. COLLAPSIBLE, RDR	11909797001

^ Instruments highlighted in grey - Active instruments in the market

^ Instruments highlighted in blue - No active instruments in the market

Instruments	Material Number
cobas 6000 core unit	07339496001
cobas 8000 core unit	04745868001
cobas 8000 core unit	05641446001
cobas c 513 analyzer	07649142001
Modular Analytics EVO Core Unit w/o ISE	04998596001
Modular Analytics EVO Core Unit with ISE 900	04998570001
Modular Analytics SWA Core Unit w/o ISE	03617483001
Modular Analytics SWA Core Unit with ISE 900	03340082001
cobas e 411 rack	04775201001
Elecsys® 2010	04163184001
MPA EVO / SBU - MA / - cobas 8000 / - cobas p 501-	05968046001
URISYS 2400	03051323001
cobas u 601 urine analyzer	06390498001
cobas u 701 microscopy analyzer	06390501001
COBAS INTEGRA® 800 analyzer / instrument	28122474001
cobas 6800	05524245001
cobas 8800	05412722001
cobas p680	06570577001
cobas p471 centrifuge unit	05088062001
cobas p671 centrifuge unit	05087996001
cobas p312 pre-analytical system	06459315001
cobas p512 pre-analytical system	05083435001
cobas p612 pre-analytical system	05082579001
RSA Pro	05082579001
RSD Pro	05083435001
RSD 800	03750221001
RSD 800A	03750264001
Aliquoter VSII	04634764001
LABexon TW-600	05848628001
LABexon TI-750	05848644001
STA_R	04173902001
STA_R EVOLUTION	04684699001
cobas p501 post-analytical unit	05158494001
cobas p701 post-analytical unit	05349966001

Addendum

Cleaning rack trays

Revisions

This chapter contains a revision/addition to the **Maintenance - As needed** section, which was necessary due to missing information.

Table of contents

Overview	4
Cleaning the rack tray	5

Overview

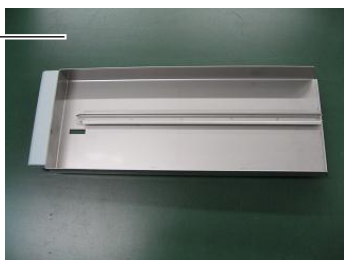
Roche recommends that you familiarize yourself with the new and/or revised content provided in this chapter.



If you print these pages, Roche recommends printing them single-sided. In this way, you can easily insert the new and/or revised content in its appropriate locations in the existing document.

This document describes the procedure for cleaning sample rack trays as shown in the examples below. Even if your rack tray looks different to the examples illustrated, to avoid personal injury carefully follow this procedure when cleaning sample rack trays.

A



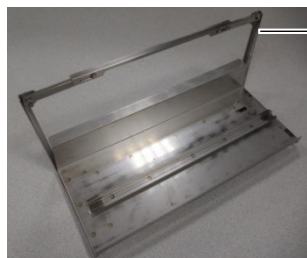
B



C



D



A Rack tray - shape 1 **C** Rack tray - shape 3

B Rack tray - shape 2 **D** Rack tray - shape 4

Examples of different rack tray types

If the sample rack tray is dirty, it is necessary to clean it using the procedure described below.

In this section

Cleaning the rack tray (5)

Cleaning the rack tray

Spills on the rack tray surface can be biohazardous. Clean up all spills. The cleaning procedure described below is the same for all types of rack trays.

⚠ WARNING

Personal injury due to the edges on the rack tray's center guide rail.

The edges on the rack tray's center guide rail may cause personal injury.

- ▶ Avoid contact with all edges, even when wearing lab gloves.
 - ▶ Wear protective equipment such as lab gloves.
 - ▶ Carefully observe all instructions given in this addendum.
-

⚠ CAUTION

Infectious samples

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples containing material of human origin are potentially infectious.

- ▶ Follow Good Laboratory Practices, especially when working with biohazardous material.
 - ▶ Keep all covers closed while the system is operating.
 - ▶ Before you work with an opened cover, always switch off the instrument or select a mode appropriate for the particular maintenance action.
 - ▶ Wear appropriate personal protective equipment.
 - ▶ If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
 - ▶ If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
Consult a physician.
-

⚠ CAUTION**Skin inflammation or injury**

Direct contact with reagents, wash solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- ▶ When you handle reagents, exercise the precautions required for handling laboratory reagents.
 - ▶ Wear appropriate personal protective equipment.
 - ▶ Observe the instructions given in the Instructions for Use.
 - ▶ Observe the information given in Material Safety Data Sheets (available for Roche Diagnostics reagents and wash solutions).
 - ▶ If reagents, wash solutions, or other working solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
Consult a physician.
-

⚠ CAUTION**Fire and burns**

Alcohol is a flammable substance.

- ▶ Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance or checks that involve alcohol.
 - ▶ When you use alcohol on or around the system, use no more than 20 mL at a time.
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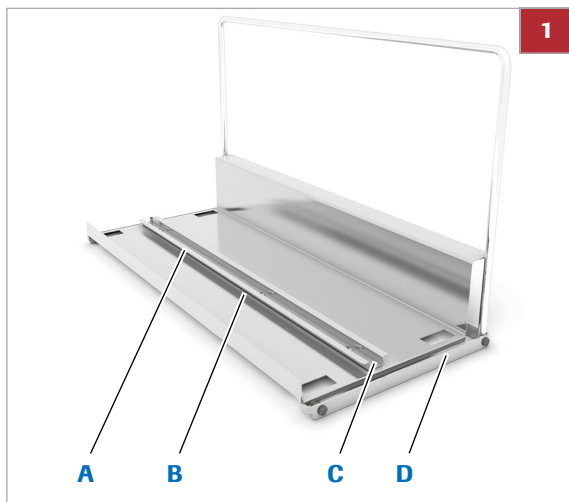
- ☐ Lint-free cloth
- ☐ Cotton swab
- ☐ Alcohol
- ☐ Personal protective equipment such as lab gloves, lab coat, and eye protection



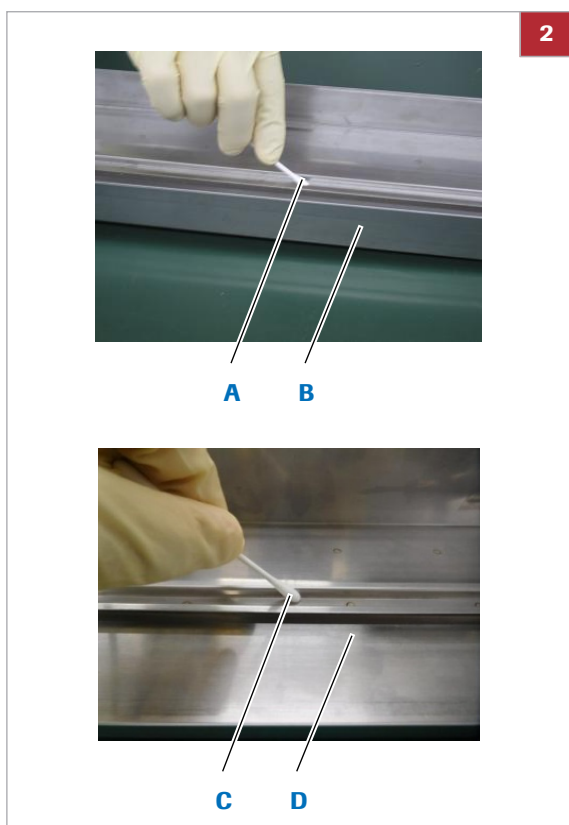
- ☐ The instrument or module is in **Standby** mode or when the green status LED is ON.

► To clean the rack trays

- 1 Use personal protective equipment when cleaning the rack trays.

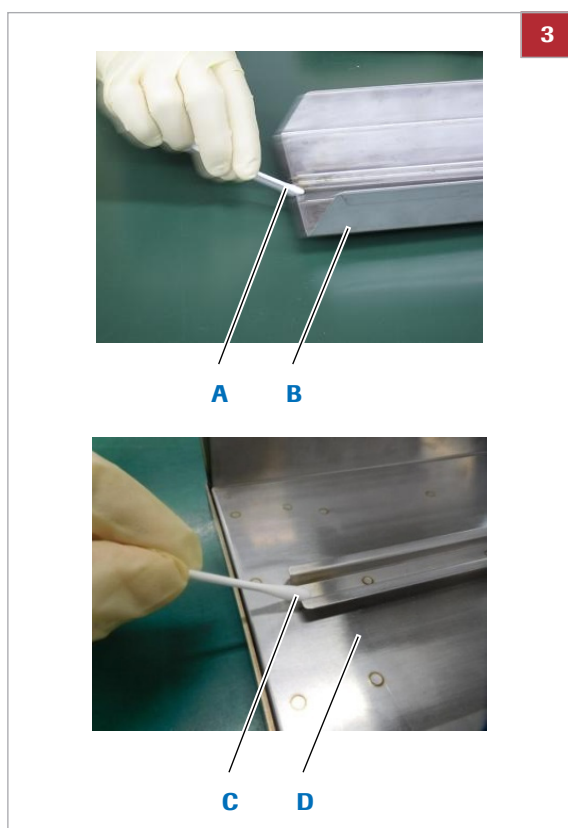


- A** Rail edge **C** Rail center
B Rail groove **D** Rack tray



- 2 Wipe the rail center in both directions with a cotton swab moistened with alcohol.
 - If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.
 - ❗ Take care not to sustain injuries by coming into contact with the edges.

- A** Cotton swab (rack tray shape 1 and 2) **C** Cotton swab (rack tray shape 3 and 4)
B Rack tray (rack tray shape 1 and 2) **D** Rack tray (rack tray shape 3 and 4)



3

3 Wipe the rail edge in both directions with a cotton swab moistened with alcohol.

- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.

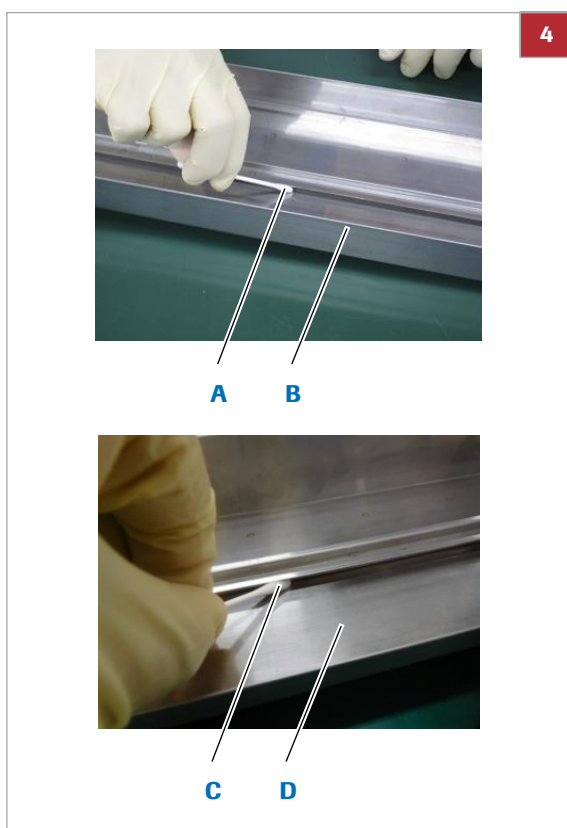
ⓘ Take care not to sustain injuries by coming into contact with the edges.

A Cotton swab (rack tray shape 1 and 2)

B Rack tray (rack tray shape 1 and 2)

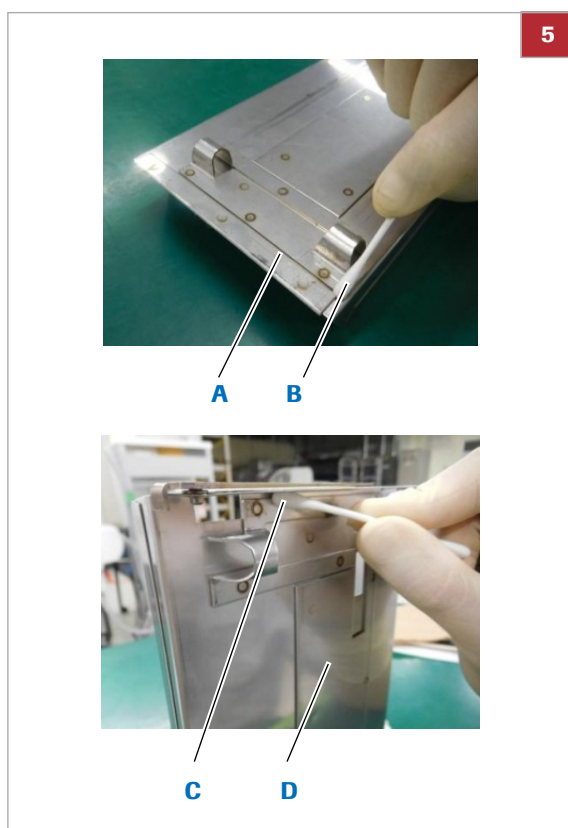
C Cotton swab (rack tray shape 3 and 4)

D Rack tray (rack tray shape 3 and 4)



- 4** Wipe the rail groove in both directions with a cotton swab moistened with alcohol.
- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.
 - ❗ Take care not to sustain injuries by coming into contact with the edges.

- A** Cotton swab (rack tray shape 1 and 2) **C** Cotton swab (rack tray shape 3 and 4)
- B** Rack tray (rack tray shape 1 and 2) **D** Rack tray (rack tray shape 3 and 4)



5

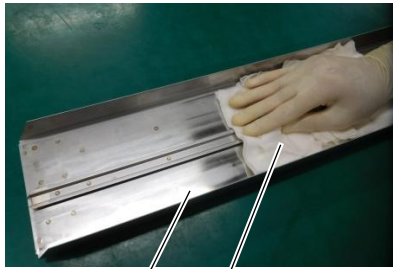
5 Wipe the edges on the bottom of the rack tray in both directions with a cotton swab moistened with alcohol.

- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.

ⓘ Take care not to sustain injuries by coming into contact with the edges.

- A** Rack tray (rack tray shape 1 and 2) **C** Cotton swab (rack tray shape 3 and 4)
- B** Cotton swab (rack tray shape 1 and 2) **D** Rack tray (rack tray shape 3 and 4)

6



A

B



C

D

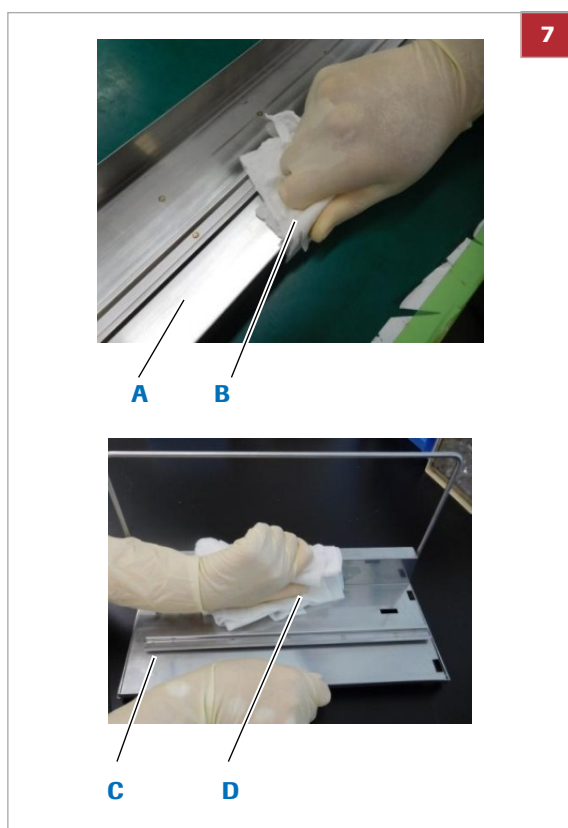
- 6** Wipe the surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.
- For rack tray shapes 1 and 2, hold the pile of lint-free cloth with your fingers and wipe the surface of the rack tray.
 - For rack tray shapes 3 and 4, hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.
 - ❗ Take care not to sustain injuries by coming into contact with the edges.

A Rack tray (rack tray shape 1 and 2)

B Lint-free cloth (rack tray shape 1 and 2)

C Rack tray (rack tray shape 3 and 4)

D Lint-free cloth (rack tray shape 3 and 4)



7

- 7 Wipe the rear surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.
- For rack tray shapes 1 and 2, hold the pile of lint-free cloth with your fingers and wipe the surface of the rack tray.
 - For rack tray shapes 3 and 4, hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.
 - ❗ Take care not to sustain injuries by coming into contact with the edges.

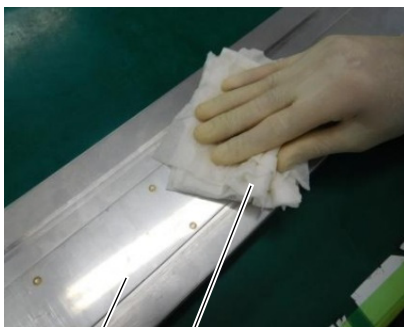
A Rack tray (rack tray shape 1 and 2)

B Lint-free cloth (rack tray shape 1 and 2)

C Rack tray (rack tray shape 3 and 4)

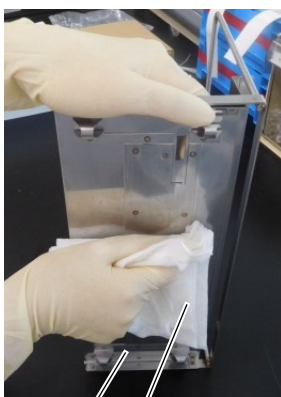
D Lint-free cloth (rack tray shape 3 and 4)

8



A

B



C

D

A Rack tray (rack tray shape 1 and 2)

B Lint-free cloth (rack tray shape 1 and 2)

C Rack tray (rack tray shape 3 and 4)

D Lint-free cloth (rack tray shape 3 and 4)

8 Wipe the bottom surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with alcohol.

- For rack tray shapes 1 and 2, hold the pile of lint-free cloth with your fingers and wipe the surface of the rack tray.
- For rack tray shapes 3 and 4, hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.

ⓘ Take care not to sustain injuries by coming into contact with the edges.

9 Visually check the rack trays.

- Make sure that there is no textile remaining on the rack tray.
- Make sure that there are no wet areas on the rack tray

