

Urgent Field Safety Notice

SBN-CPS-2017-015

CPS / Serum Work Area
Version 1
11-Jul-2017

cobas c 501/502 operator injury on USM cover 3

| | |
|--|--|
| Product Name | cobas c 501 module cobas c 502 module |
| Affected Instrument Part GMMI / Part No | USM cover 3 GMMI 05400937001 |
| Instrument/System Affected | cobas c 501 module (GMMI 04745914001) cobas c 502 module (GMMI 05964067001) |
| SW Version | Not related to the software version |
| Type of Action | Field Safety Corrective Action (FSCA) |

Dear Valued Customer,

Description of Situation

We regret to inform you that an operator was injured during a maintenance task, when removing the Ultrasonic Mixer Cover (USM cover 3) of a **cobas c** 502 module.

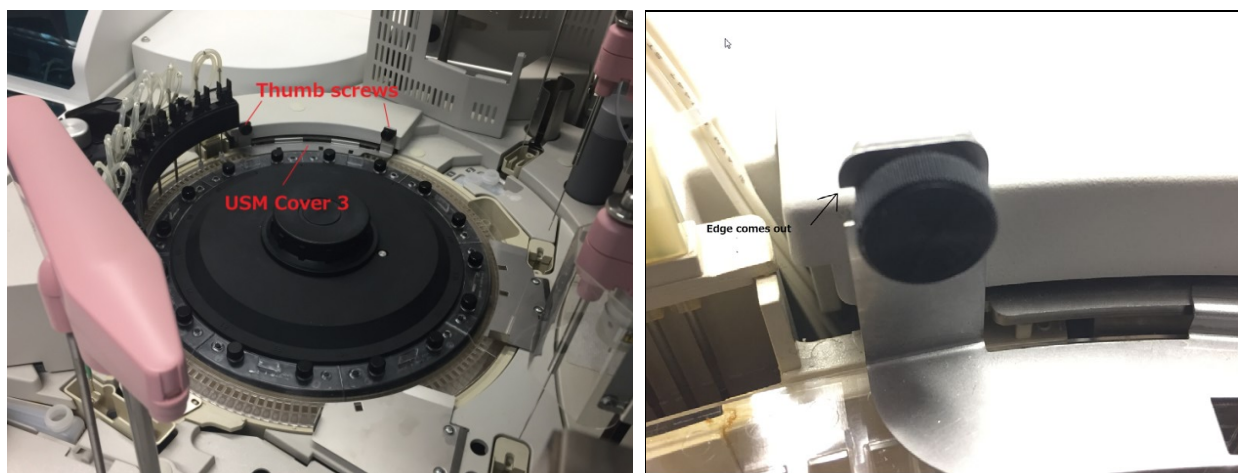
Considering that **cobas c** 501 and **cobas c** 502 modules share the same hardware, Roche Diagnostics has decided to inform and request operators of both systems to perform the related maintenance task with special caution, so as to prevent further occurrence of this issue.

When the operator cleans the incubation bath or replaces cuvettes on **cobas c** 501 and **cobas c** 502 modules, during monthly maintenance, the USM cover 3 has to be removed and its two thumb screws have to be loosened.

Detailed description of the occurrence in the field:

1. The operator was performing monthly maintenance to clean the incubation bath and replace cuvettes on a **cobas c** 502 module.
2. As a preparation step, thumb screws were being loosened to remove the USM cover 3, as illustrated below.
3. When the operator gripped the left thumb screw and tried to loosen it, she felt pain on her left thumb and found that it was already bleeding.
4. Her thumb was injured by the 90 degree-edge of the USM Cover 3, which is shown on the following picture.

cobas c 501/502 operator injury on USM cover 3



Risk Assessment:

Although the sharp edge of the USM Cover 3 is clearly visible, a medical risk due to an injury cannot be excluded.

Since the launch of the product in 2006, only one incident as above detailed has been reported.

Actions taken by Roche Diagnostics

A warning will be added to the respective Operator Manuals, which will be available by December 2017.

Notes:

The **cobas c 501** module is bound to the **cobas® 6000** analyzer series Operator's Manual.

The **cobas c 502** module is bound to the **cobas® 8000** modular analyzer series Operator's Manual.

Actions to be taken by the customer/user

Customers are advised not to overtighten the thumb screws when replacing the cover after maintenance. When removing the screws for maintenance **avoid** touching the edge of the USM Cover 3.

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. (If appropriate).

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

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the

cobas c 501/502 operator injury on USM cover 3

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