

# Field Safety Notice

## SBN-CPS-2017-015

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

### cobas c 501/502 operator injury on USM cover 3

<b>Product Name / Device Identifier</b>	<b>cobas c 501</b> module (GMMI 04745914001) <b>cobas c 502</b> module (GMMI 05964067001)
<b>Affected Instrument Part GMMI / Part No</b>	USM cover 3 (GMMI 05400937001)
<b>SW Version</b>	Not related to the software version
<b>Type of Action</b>	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.

Since both the **cobas c 501** and **cobas c 502** modules share the same hardware, we have decided to inform and request operators of both systems to perform the related maintenance task with extra caution, so as to prevent further occurrence of this issue.

Cleaning the incubation bath or replacing the cuvettes in the **cobas c 501** and **cobas c 502** modules are part of the monthly maintenance procedures. In order to do this, USM cover 3 has to be removed by loosening its two thumb screws.

#### Detailed description of the occurrence in the field:

1. The operator was performing monthly maintenance of cleaning the incubation bath and replacing the cuvettes on a **cobas c 502** module.
2. In order to perform Step 1, thumb screws needed to be loosened to remove the USM cover 3, as illustrated in Figure 1.
3. While loosening the left thumb screw, the operator felt a sharp pain in her left thumb and realized that it was bleeding. Her thumb was injured by the 90 degree-edge of the USM Cover 3, which is shown in Figure 2.

## cobas c 501/502 operator injury on USM cover 3

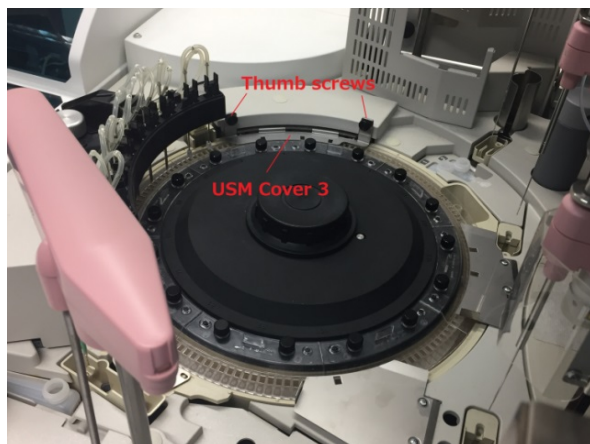


Figure 1: Picture of USM Cover 3 and its thumb screws

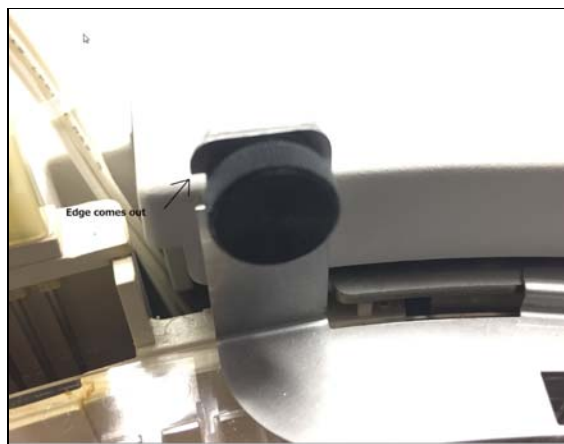


Figure 2: Sharp edge of USM Cover 3

### 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 described above 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 USM Cover 3.

## **cobas c 501/502 operator injury on USM cover 3**

### **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 thank you for your understanding and support.

Sincerely,

**Roche Diagnostics Asia Pacific Pte Ltd**

Email: [sg.regulatory@roche.com](mailto:sg.regulatory@roche.com)