

# Field Safety Notice

*SBN-CPS-2019-018*

Version 1  
07 October 2019

## Non-systemic occurrence of defective pipettes

<b>Product Name</b>	Cardiac pipettes 150 µl 20pc (int.)		
<b>Product Description</b>	150 µl Pipettes		
<b>GMMI / Part No</b>	Cardiac pipettes 150 µl 20pc (int.)	11622889190	
<b>Device Identifier</b>	<p><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></p>		
<b>System</b>	TROP T Sensitive (11621947196) (Note: cardiac pipette is included as materials for the test)		
<b>Production Identifier (Lot No./Serial No.)</b>	Lot independent		
<b>SW Version</b>	N/A		
<b>Type of Action</b>	Field Safety Corrective Action		

Dear Valued Customer,

In the past months we have received 9 customer complaints worldwide for Cardiac Pipettes (out of more than 11 million distributed single syringes). The following issues were observed: 8 cases where the needle came off the pipette and 1 case where the needle became stuck in a sample tube. The manufacturer has carried out an investigation and confirmed these findings. In all related complaints the issue was detected by the user and no injury occurred.

Due to the residual medical risk associated with this issue, customers using the affected product must be informed using this FSN.

# Non-systemic occurrence of defective pipettes

## **Actions taken by Roche Diagnostics**

Roche will update the operator's manual for **cobas h 232** as well as the method sheet of the Trop T visual strip. In order to provide guidance how to recognize and handle a defective pipette, the warning message below will be added:

### **WARNING**

Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines).

## **Actions to be taken by the customer/user**

Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines).

## **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](mailto:sg.regulatory@roche.com)