

Urgent Field Safety Notice

SBN-RTD-2019-001

RTD / VENTANA HE 600 system
Version 1
04-Oct-2019

VENTANA HE 600 system: Fluid Leak and Risk of Burnt Components

Product Name	VENTANA HE 600 system
GMMI / Part No	VENTANA HE 600 system: 06917259001
Device Identifier (GTIN)	04015630976010
Production Identifier (Lot No./Serial No.)	Not Applicable
SW Version	Not Applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche Tissue Diagnostics received notification from the field relating to a burnt coverslip module. No injuries were reported. Upon investigation it is determined that there was a leak in the staining module of the VENTANA HE 600 system. The fluid travelled down to the electrical wiring connector of the Coverslipper solvent shield printed circuit board assembly (PCBA). This caused an electrical short condition and damage to the electrical components. This resulted in burnt components.

Actions taken by Roche Diagnostics (if applicable)

This situation represents a potential safety concern. Considering the findings of the local investigation, the fact that the incident was localized, no injury occurred, and the mitigations currently in place, there is a remote probability that use of the VENTANA HE 600 system would result in adverse health consequences.

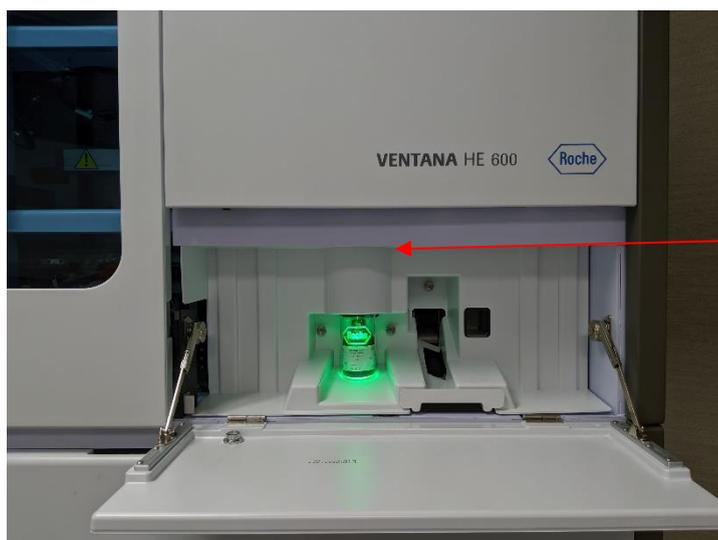
The root cause investigation, including the cause for the Cleaning Solution leak, is on-going and suggests the cause of the event has multiple contributing factors, including the 65 Micron filter and the Stainer Exchange valve assembly in the Cleaning Solution fluidics line.

Local Roche Field Service Engineers will remove the cable that conducts electricity to the Coverslipper Module LED PCBA, proactively replace the Stainer Exchange Valves, and proactively replace the 65 Micron Filters in the Cleaning Solution fluidics line. Site visits will be scheduled as appropriate.

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Actions to be taken by the customer/user

Customers can continue using the instrument as they would normally do. If evidence of droplets on the instrument coverslip module are observed during normal operation, please stop instrument operation, unplug the instrument, and contact your local Roche Service organization, immediately.



If droplets are observed on the top part of the coverslip module, stop instrument operation, unplug instrument, and contact your local Roche Service organization

The LED light indicates the status of the coverslip activator bottle (PN 07534396001). Following the removal of the Coverslipper Module LED PCBA cable, the green light on the coverslipper activator shield will not operate as expected. The green light will be off.

Removing the cable will cause a change in operator usability as the LED Shield will no longer display the Steady Green and Flashing Green states as designed. Operators can refer to the Graphical User Interface for indications of solvent availability in the coverslip activator bottle.

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Operators can refer to the Graphical User Interface for indications of solvent availability in the coverslip activator bottle.

Table indicating coverslip activator fluid status on the VENTANA HE 600 system graphic user interface (GUI)

Icon	Color	State	Meaning
	Blue with Check mark	Coverslip activator bottle is Full.	Ready to use.
	Red	Coverslip activator bottle is empty OR it has a closed/invalid RFID tag.	The activator bottle must be replaced.
	Red with X mark	Coverslip activator bottle has an expired (date) RFID tag.	The activator bottle must be replaced.

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	Grey	Coverslip activator bottle is missing (not present).	Load activator bottle.
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Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

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 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.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com