Urgent Field Safety Notice

SBN-RDS-Pathology Lab-2022-002

RDS/Pathology Lab/ VENTANA HE 600 System
Version 1

VENTANA HE 600 System: Instrument Leak & Fire

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

Dear Valued Customer,

Description of Situation

Roche has confirmed 2 complaints regarding fluid leaks within the middle stainer module of the VENTANA HE 600 that likely resulted in electrical shorts at the plate heater connections that then escalated into fires. No physical harm or injury was reported.

In both cases, the fire originated from the middle stainer modules at the backside of the connectors for the Plate heaters.

A third party fire analysis investigation was conducted for both the cases. An internal investigation has been initiated and is currently ongoing for both.

This situation represents a potential safety concern.

- Fluid accumulation within the instrument and escape is not easily recognizable by the operator. However, the smoke and odor caused by an electric short would likely be noticeable if the operator is close to the device.
- There have been 2 fire events at heater pads as a result of fluid leaks within the middle stainer module of the HE 600 instrument, out of a total of 709 active instruments in the install base. The two events occurred at 247 and 254 weeks, or about 4.74 and 4.87 years, from the date of each instrument's installation.
- Because the fire and any associated smoke could extend beyond the instrument, there is a risk of injury, potentially serious, from smoke inhalation and/or direct contact with the fire itself. Routine fire/smoke safety and evacuation procedures mitigate the risk of injury. Additionally, given the ability to retest the patient sample, the probability that this failure mode would result in adverse health consequences for patients is estimated as very low.

No injuries have been reported to date.

VENTANA HE 600 system: Instrument Leak & Fire

Actions taken by Roche Diagnostics

A Corrective and Preventive (CAPA) investigation has been initiated and is ongoing to identify the root cause for these events. The initial investigation in both cases indicates the most likely cause of these events was a leak within the middle stainer module that allowed conductive liquid to come into contact with the plate heater and its connectors. Further information will be provided after completion of the CAPA investigation.

The following actions will be completed by Roche that will help in containment and mitigations of the risks.

As part of initial mitigation, a stainer temperature monitoring update will be introduced for all instruments. The stainer monitoring update will enable the software to monitor the temperature of all four of the instrument's stainer plate heaters immediately after a tray completes a staining run. An error message 3022 will be displayed to the users. Customers should be advised to immediately power off the instrument and contact Roche support on receiving the 3022 error message. This error message will continue to appear until the instrument is repaired. Roche will subscribe and monitor the Error Messages received by the customer instruments to ensure Field Service Engineers (FSEs) are aware and can take necessary actions as soon as possible when the error is triggered. A Roche service representative will install the software update and these actions are aimed to be completed by 31-Aug-2022.

To further mitigate the issue, plate heater connectors will be coated with Liquid Electrical Tape (LET). The application of LET on the connectors in the heating pads in each staining module will be implemented in manufacturing as well as in the field. A Roche service representative will ensure that the actions will be completed and these actions are aimed to be completed by 30-Sep-2022.

An additional software update to turn off the power to the stainer will be available later. This functionality will be part of v1.10.2 software release as part of further mitigations. The development of this software is in progress the availability date will be communicated once available.

VENTANA HE 600 system: Instrument Leak & Fire

Actions to be taken by the customer/user

Please do not leave the instrument unattended when the power is on. Do not place the system in stand-by mode overnight when unattended until further mitigation actions have been implemented. Please turn off the power of the instrument when it is unattended.

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