

Urgent Field Safety Notice

SBN-RDS-Pathology Lab-2022-001

RDS / Pathology Lab

Version 2

BenchMark ULTRA & DISCOVERY ULTRA Electrical Short

Product Name

BENCHMARK ULTRA STAINER MODULE

DISCOVERY ULTRA (RUO)

**GMMI / Part No
Device Identifier**

BENCHMARK ULTRA STAINER MODULE

GMMI: 05342716001

UDI: 04015630981052

DISCOVERY ULTRA (RUO)

GMMI: 05987750001

UDI: 07613336157923

**Production Identifier
(Lot No./Serial No.)**

All BenchMark ULTRA instruments with serial number 322030 and earlier.

All DISCOVERY ULTRA instruments with serial number 330018 and earlier.

Note: This version 2 of the Field Safety Notice applies to BenchMark ULTRA instruments with serial numbers between 320873 and 322030 and DISCOVERY ULTRA instruments with serial numbers between 319911 and 330018.

SW Version

Not Applicable

Type of Action

Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

BenchMark ULTRA & DISCOVERY ULTRA Electrical Short

Roche received a complaint reporting a fluid leak within the BenchMark ULTRA instrument that created an electrical short inside the instrument. The instrument's General Purpose Input/output (GPIO) board's Printed Circuit Board (PCB) had an electrical short resulting in smoke and fire. Please note that no evacuation was needed and there was no injury to users.

In the reported case, the origin of the electrical short was determined to be at the J1 connector of the GPIO board in the lower rear portion of the BenchMark ULTRA instrument.

This situation represents a potential safety concern. Should the fire and any associated smoke extend beyond the instrument there is risk of injury, potentially serious, from smoke inhalation and / or direct contact with the fire itself. However, the probability that this failure mode would result in adverse health consequences is estimated as remote based on:

- The design of the BenchMark ULTRA instrument limits the chances of a fire escalating due to limited fuel available (plastic) and the fact that it is mounted to metal. Although not easily detectable by the operator, there are several mitigating factors that might mitigate the product risk. The electronics are not in a direct vertical path, they are protected from fluid by the reagent drip tray, and they are tucked in at the back of the tray. The instrument was designed to and has been certified to meet the standards of IEC/EN 61010-1, which include Section 6, Protection against electric shock and Section 9, Protection against the spread of fire.
- No injuries have been reported to date.
- This event does not have significant impact beyond laboratory users based on all the mitigations in place in the laboratory.

Actions taken by Roche Diagnostics (if applicable)

Additional analysis and investigation is ongoing to determine the root cause(s). Further information will be provided after completion of the investigation. For the time being, considering all the mitigations mentioned before, the following short-term actions are to be followed:

Local Field Service Engineers will contact the customers and perform specific service actions during a site visit, such as, inspecting all devices for any signs of current and/or past fluid leaks, cracks, or clogging and clean & replace any GPIO boards that have these signs. Additionally, the Field Service Engineers will rearrange cables that plug into port J1 of the left as well as right GPIO boards of the instruments, to introduce a drip loop to each cable in order to redirect fluids away from the boards at J1 position, to help mitigate the issue.

Please note it is planned to complete the needed action by 30-Sep-2023.

BenchMark ULTRA & DISCOVERY ULTRA Electrical Short

Actions to be taken by the customer/user

Customers can continue using the instruments as they would normally in accordance with the instrument Operator's Manual. Please stop using the system and turn off the power to the instrument in the event of a visible fluid leak outside of the instrument, and contact your local Roche Service organization, immediately.

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