

Urgent Field Safety Notice

SBN-RTD-2020-001

RTD / BenchMark ULTRA
Version 1
18-Aug-2020

BenchMark ULTRA: Fluid Leak and Risk of Electrical Short Circuit

Product Name	BENCHMARK ULTRA STAINER MODULE DISCOVERY ULTRA (RUO)
GMMI / Part No	BENCHMARK ULTRA STAINER MODULE
Device Identifier	GMMI: 05342716001 UDI: 04015630981052 DISCOVERY ULTRA (RUO) GMMI: 05987750001 UDI: 07613336157923
Production Identifier (Lot No./Serial No.)	All serial IDs
SW Version	Not Applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Complaints were filed reporting fluid leaks within BenchMark ULTRA instruments that created an electrical short inside the power socket, which over time generated heat, smoke, and eventually burning and melting of the electrical cord connector and socket. The events were localized to the electrical cord connector and socket, and there were no injuries.

Description of Situation

In the reported cases, the primary leak sources originated from fluidic components and caused an electrical short circuit in the EMI (Electromagnetic Interference) line filter leading to burning and melting of the electrical cord connector and socket. Through the extent of the investigation, it was determined that waste tub overflow events may also result in fluids migrating into the power socket.

This situation represents a potential safety concern.

The probability that this failure mode would result in adverse health consequences is estimated as remote based on:

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- Detailed review of the available data indicates that the probability of an EMI filter failure over an estimated 10 year period on a given instrument is 0.006%, at 95% confidence.
- The design of the power socket limits the chances of a fire escalating due to limited fuel available (plastic) and the fact that it is mounted to metal. None of the reported failures resulted in damage away from the power socket itself.
- No injuries have been reported to date.

Actions taken by Roche Diagnostics (if applicable)

CAPA investigations have been conducted to identify the root cause for these events. The root cause specific to the electrical aspects of the BenchMark ULTRA instrument are completed. The investigation identified there was a fluid leak that resulted in fluids getting inside the power cord connector to the instrument. Once inside the connector, the fluid created an electrical connection between the terminals within the AC power receptacle, which over time caused the external power connector to burn.

The investigation regarding the cause of the fluid leak indicates the potential for certain tube fittings to fracture or break, which may lead to a leak. Additional analysis and investigation is ongoing to determine the root cause(s).

Local Field Service Engineers will perform specific service actions, including the installation of the power connector shield, which will prevent fluid entry into the power cord connection and socket, inspection of specific instrument parts for signs of cracks and fluid leaks, and completion of the Waste Tub and Filter Upgrade, if necessary.

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 fluid leak, 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.

BenchMark ULTRA: Fluid Leak and Risk of Electrical Short Circuit

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com