



bioMérieux Nordic countries
Customer Service Department
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Möln dal, DD M YYYY

URGENT FIELD SAFETY NOTICE
FSCA 5761-2 – Increased Risk of Power Short with the BIOFIRE® FILMARRAY® TORCH System

To the attention of the Laboratory Medical Director

Product Reference Number(s): HTFA-ASY-0104, HTFA-ASY-0001
Device Name: FILMARRAY TORCH System
Lot/Serial Numbers: All FILMARRAY TORCH System Bases

Dear customer,

The purpose of this letter is to **update you with revised information (shown in red)** of a product correction involving the BIOFIRE® FILMARRAY® TORCH System.

bioMérieux has identified an increased risk of degradation of the power entry switch of the TORCH Base. This increased risk may be seen on systems that are power cycled (shutting down the system and then turning it on again) frequently.

When turning on BIOFIRE TORCH systems, arcing inside of the power switch may result in carbon build-up on the switch contacts. The carbon build-up may lead to excess heating inside of the power switch, subsequently leading to deformation of the power switch case. The deformation can create an opportunity for a power switch electrical short. In addition to an electrical short, deformation may result in an open circuit causing the power switch to fail. This event would only occur after the product is in use.

Our preliminary CAPA investigation confirmed that only TORCH Bases with more than 6 modules would be at risk for deformation. In the event of degradation or deformation, other risks could include but are not limited to:

bioMérieux Nordic Countries

HEAD OFFICE SWEDEN
bioMérieux Sweden AB
Visiting address:
Entreprenörstråket 10
SE-431 53 Möln dal, SWEDEN
Phone. +46 (0)31-688490

POSTAL ADDRESS FOR ALL
NORDIC COUNTRIES:
bioMérieux Sweden AB
Förändringens gata 10
SE-431 53 Möln dal, SWEDEN
Org nr. 556266-0653 VAT SE556266065301

DENMARK
bioMérieux Danmark ApS
Tel. 70 10 84 00
Vat nr/Org nr: 10062462

FINLAND
bioMérieux Suomi Oy
Puh: 09-8545 600
VAT nr/Org.nr: FI05277682

NORWAY
bioMérieux Norge AS
Tlf. 2152 0022
Vat.nr/Org.nr 981 062 310

- The potential for a fire if flammable material is kept near the instrument.
- Exposure to intense heat, burns, and inhalation of fumes generated by a smoking power switch.
- Electrical burns may be caused by a number of sources of electricity.
- Exposure to electrical currents could result in flash, flame, or electrical shock injuries.

To mitigate these risks, bioMérieux has revised the 'Power On' procedure for the BIOFIRE TORCH system in the Operator's Manual on pages 2-3 and 2-4. You were previously notified of the new 'Power On' procedure contained in a technical note. Please reference the technical note for detailed instructions on these procedures (<https://www.biofiredx.com/e-labeling/ITITORCH4131>).

According to the Operator's Manual, BIOFIRE TORCH systems should be reset using the 'Reset' button on a weekly basis. Utilizing the 'Reset' button will not cause degradation of the power entry switch. The updated shutdown procedure utilizing the 'Reset' button reduces the initial electrical draw, which mitigates the risk of carbon build-up on the switch contacts.

Additionally, as part of corrective actions, bioMérieux has sourced a replacement switch that is now available to update your BIOFIRE® FILMARRAY® TORCH System. Please see the 'Required actions' section below for additional information.

Required actions

In this context, we request you to take the following actions. Please:

- If a user determines that the BIOFIRE TORCH Base requires complete shutdown, each individual BIOFIRE TORCH Module must be powered down prior to turning on the BIOFIRE TORCH Base,
- 'Reset' the BIOFIRE TORCH Base weekly using the 'Reset' button.
- Move potentially flammable materials away from the TORCH system.
- Post the Technical Note on or near the TORCH system in order to continuously be aware of the 'Power On' instructions and potential issues.
- If your system has 6 or more modules installed and has been power-cycled frequently, or if the power entry switch has degraded to the point where the system should not be used, we recommend contacting the BIOFIRE support team (see contact information below) to send a field application specialist to install a replacement switch for you.
- Please complete all fields of the accompanying Acknowledgement of Receipt Form and return it to bioMérieux so that bioMérieux may acknowledge your receipt of this notification.



bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please don't hesitate to contact your local bioMérieux representative.

Regards,

Customer Service Department
bioMérieux Nordic countries

On behalf of

A handwritten signature in blue ink that reads "Eric Scott".

Eric Scott
Senior Director, Quality SLC Sites



Attachment A: Acknowledgement Form.

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**TO BE RETURNED TO YOUR BIOMERIEUX BY REPLYING TO THE EMAIL IN WHICH THIS LETTER WAS
COMMUNICATED.**

Name of Laboratory	
Address of Laboratory	
Contact information	
Customer Account Number	

I have read and acknowledge the receipt of FSCA 5761-2, regarding the Increased Risk of Power Short with the BIOFIRE® FILMARRAY® TORCH System and the available short-term preventive maintenance.

DATE..... SIGNATURE.....

It is important that you complete this Acknowledgement Form and return it to bioMérieux