

Geneva, 14<sup>th</sup> November 2023  
FSCA 5761-1

**Please distribute to the Laboratory Manager  
– URGENT FIELD SAFETY NOTICE –  
BIOFIRE® FILMARRAY® TORCH System – Part No.: HTFA-ASY-0104, Shipping Configuration  
No.: HTFA-ASY-0001  
Increased Risk of Power Short with the BIOFIRE® TORCH System**

**Acknowledgment of receipt required**

Dear valued bioMérieux Customer,

The purpose of this letter is to inform you of a product recall (correction) involving the BIOFIRE® FILMARRAY® TORCH System.

Impacted products			
Product Name	Reference Number	Lot Number/Serial Number/ Product version	Product Expiration Date (if applicable)
BIOFIRE® TORCH Base System	Part No. : HTFA-ASY-0104 Shipping Configuration No. : HTFA-ASY-0001	N/A – all serial numbers	N/A

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.

**Description of the issue**

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.

To mitigate this risk, bioMérieux has revised the 'Power On' procedure for the BIOFIRE® TORCH system in the Operator's Manual. Additionally, a technical note is available containing detailed instructions for the 'Power On' procedure (<https://www.biofire.com/e-labeling/ITITORCH4131>).

**bioMérieux (Suisse) SA**

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.

### **Required actions**

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

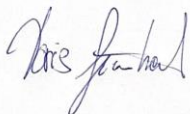
- If a user determines that the BIOFIRE TORCH Base requires complete shutdown, each individual BIOFIRE TORCH module must be powered down prior to turning on the BIOFIRE TORCH Base,
- 'Reset' the BIOFIRE TORCH Base weekly using the 'Reset' button,
- Distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative via email to [ch\\_support@biomerieux.com](mailto:ch_support@biomerieux.com) to confirm receipt of this notice. It is important that you return the acknowledgement form to bioMérieux even if you determine that this urgent product safety notice does not impact your facility.

bioMérieux is committed to providing our customers with the highest quality product possible. Thank you for your confidence in our products.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact the Scientific Customer Service of bioMérieux at 022 906 57 96.

Sincerely,

bioMérieux (Suisse) SA

A handwritten signature in black ink, appearing to read "Doris Grünbart".

Doris Grünbart  
Product Manager Molecular biology

Attachment A: Acknowledgement Form

## Attachment A: Acknowledgement Form

### URGENT FIELD SAFETY NOTICE/ CORRECTIVE NOTICE FSCA 5761-1 – BIOFIRE® FILMARRAY® TORCH – Part No.: HTFA-ASY-0104, Shipping Configuration No.: HTFA-ASY-0001 Increased Risk of Power Short with BIOFIRE® TORCH

#### Response required

In compliance with legal traceability requirements, we thank you for completing this form even if you no longer have this System.

Please return the form to your customer service  
Per email [ch\\_support@biomerieux.com](mailto:ch_support@biomerieux.com)

Name of the laboratory: \_\_\_\_\_

Contact person: \_\_\_\_\_

City and postal Code: \_\_\_\_\_

Customer No.: \_\_\_\_\_

With your signature you confirm that you have received the urgent field safety notice regarding the „FSCA 5761-1 – BIOFIRE® FILMARRAY® TORCH – Part No.: HTFA-ASY-0104, Shipping Configuration No.: HTFA-ASY-0001 - Increased Risk of Power Short with BIOFIRE® TORCH “.

You further confirm that you will implement the required actions, as indicated in the Urgent Field Safety Notice. If not, please indicate the reasons in the Comments section below.

Comments

REF #	Product Name	Serial number #/ Version number	Quantity impacted	Quantity corrected**	Quantity returned*
Part No. : HTFA-ASY-0104, Shipping Configuration No. : HTFA-ASY-0001	BIOFIRE® TORCH Base System	All serial numbers	All BIOFIRE® TORCH Base Systems	N/A	N/A

\* Quantity returned to bioMerieux subsidiary or distributor

\*\* Quantity corrected include software updates or instruments corrections.

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