



نتقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 275 dated 21/12/23 Regarding NCMDR Field Safety Notice of BIOFIRE TORCH Base System from (mfr: BioMerieux Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: 100 - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 2751/2023

08 -06-1445 H

21 -12-2023

Field Safety Notice of BIOFIRE TORCH Base System from BioMerieux Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19805
Product	BIOFIRE TORCH Base System.
Description	Qualitative multiplexed nucleic acid-based test.
Manufacturer	BioMerieux Inc.
Local agent	Al Hashar Pharmacy.
The affected products	Part No. : HTFA-ASY0104 Shipping Configuration: No. : HTFA-ASY-0001 All Serial numbers
Reason	When turning on BIOFIRE TORCH systems, arcing inside of the power switch ultimately cause deformation may result in an open circuit causing the power switch to fail. This event would only occur after the product is in use.
Action	1. Please follow the required actions in the attachment. 2. 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). 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubate

Director General



PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: 393 مسقط - الرمز البريدي: 100 - هاتف: 22357111 - فاكس: 22358489

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padc@moh.gov.om

IMPORTANT:
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

To the attention of the Laboratory Medical Director

October 2023
bMx local contact information
(to be adapted at local level)

Our reference: FSCA 5761-1

Impacted products (to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)			
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

Dear Valued Customer,

The purpose of this letter is to inform you of a product recall (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.

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.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.

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 (to be adapted at local level)* 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 correction notice/information/recommendation *(to be adapted based on issue)* does not impact your facility.

Local legal mentions to be added if necessary at local level (e.g. in case of recall, reporting to NCA, recall methods)

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 contact *your local bioMérieux Customer Service representative (to be adapted at local level)*.

Sincerely,



Senior Director, Quality SLC Sites



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY/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**

TO BE RETURNED TO YOUR *BIO MÉRIEUX* CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)
AT THE FOLLOWING
FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXXX

Name and Address of the laboratory	
Contact information	
Customer Account Number	

Local legal mentions to be added if necessary at local level)

- I am not impacted by the issue. Please provide rationale:
- I have implemented the required actions.

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.....

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