

Lab Location: SGMC & WOMC
Department: Core Lab- Microbiology

Date Distributed: 11/22/23
Due Date: 11/30/23
Implementation: **12/1/23**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
SGMC.M 1019 BioFire® FilmArray® Torch Systems Maintenance Biofire ® FilmArray Torch Maintenance Record
Description of change(s):
Weekly Maintenance was updated to include a weekly reset. Monthly Maintenance was updated to include monthly reboot with specific start up instructions. Power down and up instructions updated in response to URGENT: MEDICAL DEVICE CORRECTION letter from BioFire due to risk of a power short in the system (see appendix A attached to SOP)

Document your compliance with this training update by taking the quiz in the MTS system.

SGMC.M 1019 BioFire® FilmArray® Torch Systems Maintenance

Copy of version 2.0 (in review)

Effective Date 12/1/2023

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Printed By Demetra Collier (110199)

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Core Lab Approval	4/25/2023	1.0	<i>Robert SanLuis</i> Robert SanLuis	
Periodic review	QA approval	4/25/2023	1.0	Demetra Collier (110199)	
Approval	Lab Director	4/22/2021	1.0	Nicolas Cacciabeve	
Approval	Micro Director approval	4/21/2021	1.0	Ronald Master	
Approval	QA approval	4/21/2021	1.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	4/21/2021	4/22/2021	Indefinite

Linked Documents

- AG.F 516 BioFire® FilmArray®Torch Maintenance Record

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Non-Technical SOP

Title	BioFire® FilmArray® Torch Systems Maintenance	
Prepared by	Leslie Barrett	Date: 4/21/2021
Owner	Ron Master	Date: 4/21/2021

Laboratory Approval		
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:	Local Effective Date:	

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1. PURPOSE

This procedure describes the required maintenance for the BioFire® FilmArray® Torch Systems.

2. SCOPE

This procedure applies to the BioFire® FilmArray® Torch Systems.

3. RESPONSIBILITY

The supervisor is responsible for ensuring compliance with this SOP.

Core Laboratory personnel are responsible for performing and documenting the tasks at the specified time frames.

4. DEFINITIONS

None

5. PROCEDURE

Weekly:

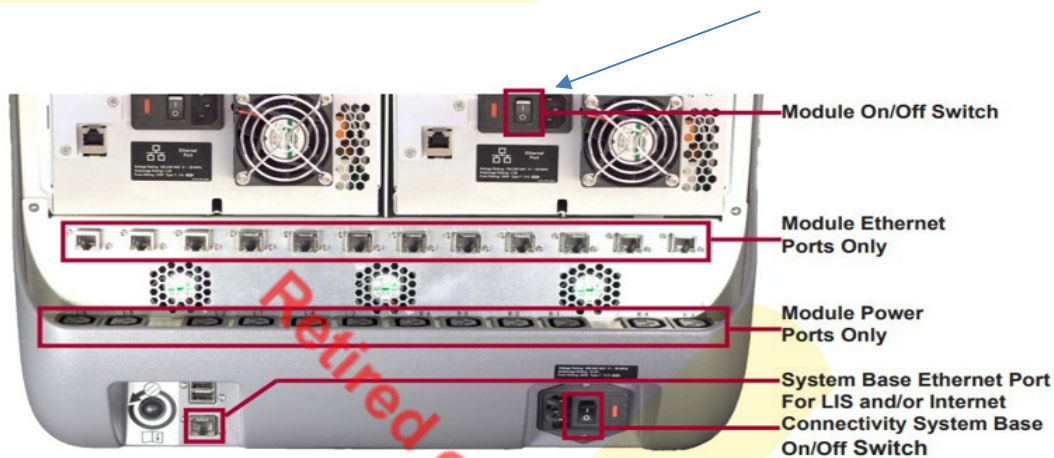
1. Decontaminate Loading Station: soak loading station in 10% bleach 15 min, soak in water twice to remove bleach.
2. Decontaminate Instrument surfaces: wipe instrument surfaces and touch screen with 10% bleach followed by wiping with water to remove bleach. Do not drip bleach or water inside instrument when cleaning surfaces.
3. Reset the System Base: This action should be performed **only with the reset button** on the back of the System Base and NOT the System Base On/Off switch.



Monthly:

1. Check filters: clean or replace as needed
2. Archive the previous months data to a USB drive.
 - a. Insert a removable drive(s) into an available USB port on the front of the System Base.
 - b. Navigate to the Settings menu from the toolbar.
 - c. Select Archive.
 - d. Select Archive Runs to display a calendar.
 - e. Select a date parameter on the calendar. This parameter means that all runs on or before that date will be archived.
 - f. If more than 100 runs are selected, archived runs are sorted into files containing 100 runs each.
 - g. Select Next to choose the location and filename for the archived runs.
 - h. Select Yes to launch the archiving process. The date and time of the start will be recorded in the Archive Log. The archive process executes in the background and the status of the archive is seen in the status message on the Archive Log page. The operator may navigate to the Dashboard to perform other tasks.

3. **Shut down and reboot system:** Turn off the power switch on the Torch instrument by first pressing the button switch on the back, right panel. Wait until the screen turns off (black). Then turn off the instrument toggle switch on back, left panel. **Before powering on the System Base, ensure that the On/Off Switches on all connected Modules are in the “off” position.** Wait at least 1 minute before turning the instrument on with the toggle switch on back. **After the System Base has been powered on, then each connected Module can be powered on** and the cable shrouds installed.



Documentation: Record completion of each task on the maintenance form.

6. **RELATED DOCUMENTS**

FilmArray Torch Maintenance Record (AG.F516)

7. **REFERENCES**

FilmArray® Torch Specification Sheet, HTFA-PRT-0058-01, QS-339B-01
 BioFire ®FilmArray® Torch Base Power Entry Switch Technical Note BFR0002-4131-01, QS-339J-01

8. **REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
1	11/21/23	Section 5: revised weekly and monthly maintenance to include weekly reset and monthly power up procedure per Biofire Technical note Section 7: Added reference to Technical Note Section 9: Added appendix A Medical Device correction letter.	D Collier	V. Ponraj

9. **ADDENDA AND APPENDICES**

Appendix A: Medical Device Correction Letter

Appendix A

October 2023

URGENT: MEDICAL DEVICE CORRECTION FSCA 5761

Increased Risk of Power Short with the BIOFIRE® FILMARRAY® TORCH System

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.

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.

Actions to be taken by customer:

- 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, and
- Please complete the accompanying Acknowledgment of Receipt Form and return it to bioMérieux so that bioMérieux may acknowledge your receipt of this notification.

Actions to be taken by bioMérieux:

bioMérieux is currently performing Corrective and Preventive Actions (CAPA) as part of the ongoing investigation.

Please contact customer support at biofiresupport@biomerieux.com or via telephone by dialing +1.800.736.6354 and selecting option 5 for Product Technical Support with any questions or concerns.

Adventist HealthCare
Site: Shady Grove Medical Center, White Oak Medical Center

Title: BioFire® FilmArray® Torch Systems
Maintenance

In addition to reporting to bioMérieux, adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Thank you for your acknowledgment of this matter.

Sincerely,



Aneta Waliszewski
Senior Director, Quality SLC Sites

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Biofire ® FilmArray Torch Maintenance Record

- Shady Grove Medical Center
- White Oak Medical Center

Month: _____ Year: _____ Instrument Serial Number: _____

Weekly	Week 1		Week 2		Week 3		Week 4		Week 5	
	Date	Tech Code	Date	Tech Code	Date	Tech Code	Date	Tech Code	Date	Tech Code
Clean loading station (10% bleach for 10 minutes followed by water rinse)										
Clean instrument (10% bleach followed by water wipe)										
Perform weekly reset of the System Base (using the reset button only)										
Monthly										
Archive data	Date:		Tech Code:							
Shut down and reboot system (See SOP for power up procedure)	Date:		Tech Code:							
Check filters – clean or replace as needed	Date:		Tech Code:							

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Month: _____ Year: _____

Weekly	Week 1		Week 2		Week 3		Week 4		Week 5	
	Date	Tech Code	Date	Tech Code	Date	Tech Code	Date	Tech Code	Date	Tech Code
Clean loading station (10% bleach for 10 minutes followed by water rinse)										
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Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: