BIOFIRE® FILMARRAY® TORCH Specification Sheet

TECHNICAL NOTE

FILMARRAY TORCH Overview

The BIOFIRE FILMARRAY TORCH is an automated in vitro diagnostic (IVD) device intended for use with FDA cleared IVD FilmArray panels. The BIOFIRE TORCH is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The BIOFIRE TORCH interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The BIOFIRE TORCH software automatically determines the results and provides a test report.

The BIOFIRE TORCH System builds on the technology of the BIOFIRE FILMARRAY 2.0 and features a modular, scalable design. It begins with a System Base that includes two BIOFIRE TORCH Modules and runs BIOFIRE TORCH software to control operations and manage data. Additional capacity can be added by stacking up to five Duplex Module enclosures, each capable of housing two more TORCH Modules for a total of up to twelve Modules per system. Each Module functions independently and can be accessed at random to run a single BIOFIRE reagent pouch. The system software coordinates the activity of all Modules while collecting, analyzing, and storing the resulting data.

TORCH System Specifications

Sample Description	• One sample capacity per Module (with up to 12 samples per BIOFIRE Torch)
Run Time	• Sample run time about one hour
User Interface	• System Base with touch screen and barcode scanner
Data Output	• Automatic analysis with end-of-run interpretive reports
Fluorescence Acquisition	• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging

Temperature Control	• Operating temperature 15°C to 30°C
	• Peltier devices:
	  ○ Ambient to 100°C
	  ○ Ramp rate from 0.1–0.5°C /sec on melt

Operations Specification	• 15°C to 30°C @ 20 to 80% relative humidity (non-condensing) • -16m to 3048m • Indoor use only

TECHNICAL NOTE

BioFire Defense, LLC
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<table>
<tr><td>Shipping Specifications</td><td>

- -30°C to 38°C @ 5 to 85% relative humidity (non-condensing)
- -16m to 10,600m

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<tr><td>Power Requirements</td><td>
<table>
<tr><th rowspan="2">Configuration</th><th rowspan="2">Voltage</th><th rowspan="2">Frequency</th><th colspan="2">AC Power at 100 VAC</th><th colspan="2">AC Power at 240 VAC</th></tr>
<tr><th>Active</th><th>Apparent</th><th>Active</th><th>Apparent</th></tr>
<tr><td>Minimum (Single Module)</td><td rowspan="2">100-240 VAC</td><td rowspan="2">50-60 Hz</td><td>130W</td><td>135VA</td><td>110W</td><td>190VA</td></tr>
<tr><td>Maximum (12 Modules)</td><td>850W</td><td>935VA</td><td>775W</td><td>1100VA</td></tr>
<tr><td colspan="7">Grounded outlet requirements</td></tr>
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<tr><td>Fuse</td><td>

- 250V 3.15A Type T (Modules)
- 250V 10A Type T (System Base)

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<tr><td>Dimensions and Weight</td><td>

- 18 x 29 x 11.5 in (45.8 x 73.7 x 29.2 cm) (W x D x H;
- System Base only)
  - 4.5 in (11.4 cm) (H; Modules only)
  - 34 in (86.4 cm) max height (12 Modules)
- Weight: Approximately 268 lbs (121.6 kg) maximum:
  - System Base – 36 lbs (16.3 kg)
  - Modules – 15 lbs (6.8 kg) each
- Duplex (Module enclosure) – 6.5 lbs (~3 kg) each

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<tr><td>EMC Requirements</td><td>

- The BIOFIRE TORCH complies with the emission and immunity requirements in IEC 61326: Electrical equipment for measurement, control and laboratory use
- EMC requirements - Part 1: General requirements.

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<tr><td>Safety Requirements</td><td>

- The BIOFIRE TORCH complies with IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

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<tr><td>CPU</td><td>

- Intel®

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<tr><td>Storage and Memory</td><td>

- 512 GB hard drive or greater
- 16 GB RAM or greater

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<tr><td>Interface and Peripherals</td><td>
System Base

- 12+1 Ethernet network interfaces
- 4 USB connections or more

Module

- One Ethernet network interface

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<tr><td>Display</td><td>

- LCD: Capacitive touch screen interface

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<tr><td>Operating System</td><td>

- Microsoft® Windows® OS as released with the BIOFIRE System

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</table>

Setup Requirements

Select a clean, well-ventilated area that is large enough to fit the BIOFIRE TORCH System.

- There must be at least 1 inch (2.6 cm) between the rear panels and any other surface (such as the wall) to allow for proper air flow.
- The depth of the bench-top space should be at least 30 in (77 cm).
- The width of the bench-top space should be at least 19 in (49 cm).
- The height of the space required depends on the number of Modules installed:
    - System Base – 11.5 in (30 cm)
    - System Base + 1 Duplex – 16 in (41 cm)
    - System Base + 2 Duplexes – 20.5 in (53 cm)
    - System Base + 3 Duplexes – 25 in (64 cm)
    - System Base + 4 Duplexes – 29.5 in (75 cm)
    - System Base + 5 Duplexes – 34 in (87 cm)

The BIOFIRE TORCH complies with the emission and immunity requirements in IEC 61326. It is advisable to evaluate the electromagnetic environment prior to operating the device.

CAUTION: Do not use this device near sources of strong electromagnetic radiation (unshielded intentional radio frequency sources, for example) because these may interfere with the operation of the BIOFIRE TORCH.

Technical Support Contact Information

BioFire Defense provides the best customer support available. If you have any questions or concerns about this process, please contact the BioFire Technical Support team for assistance.

General Information
Email: support@biofiredefense.com
Phone: 1-801-262-3592
Fax: 1-801-447-6907