Manufacturer Di	Aanufacturer Disclosure Statement for Medical Device Security MDS2			
BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023	
	-		_	
Question ID	Question		See note	
DOC-1	Manufacturer Name	BIOFIRE Diagnostics, LLC The BIOFIRE SPOTFIRE System is an automated <i>in vitro</i> diagnostic (IVD) device intended for use with	-	
		compatible BioFire IVD Panels to detect multiple nucleic acid targets contained in patient specimens.		
		The BIOFIRE SPOTFIRE System interacts with the reagent pouch to both purify nucleic acids and		
		amplify targeted nucleic acid sequences using nested multiplex polymerase chain reaction (nmPCR) in		
		a closed system. The resulting PCR products are evaluated using DNA melting analysis. The software		
		automatically determines the results and provides a test report.		
		The BIOFIRE SPOTFIRE instrument is composed of one to four SPOTFIRE Modules connected to one		
		SPOTFIRE Control Station running the SPOTFIRE Application Software. The first Module is placed on top		
		of the Control Station, subsequent modules are added as desired (up to four). Each SPOTFIRE Module		
		can be randomly and independently accessed to run a reagent pouch. The SPOTFIRE software		
		(comprised of the following software components: Application Software, Panel Software, and Connectivity Software) facilitates the collection, analysis, and storage of data on the SPOTFIRE System.		
		The BIOFIRE SPOTFIRE System is designed to be used in ambulatory care and clinical acute care testing		
		environments but is expected to be used in a variety of healthcare settings.		
		SPOTFIRE software will be delivered as a single software installation image with multiple components		
		including the SPOTFIRE Application Software, SPOTFIRE Panel Software, and SPOTFIRE Connectivity		
		Software. All software will be delivered to the customer pre-installed on the control station.		
		The BIOFIRE SPOTFIRE System, hereafter referred to as the "System," is designed to run as a		
		standalone device.		
DOC-2	Device Description			
DOC-2 DOC-3	Device Description	BIOFIRE® SPOTFIRE® SYSTEM		
DOC-4	Document ID	BIOFINE' SPOTFINE' STSTEIN BFR0001-8102-01		
		BIOFIRE Technical Support		
		Email: BioFiresupport@biomerieux.com		
DOC-5	Manufacturer Contact Information	Phone: +1-801-736-6354, select Option 5		
		The System is supported in a network-connected environment for purposes such as printing or		
		archiving data to a network location. In addition, the System includes the following connectivity		
		software feature that can be enabled in a network-connected environment.		
		The System can be configured to bidirectionally interface with a Point of Care Data Manager to		
	Intended use of device in network-connected	transfer test results from the System. This optional software feature requires a connection to the local		
DOC-6	environment:	area network (LAN) at the facility.		
DOC-7	Document Release Date	2/22/2023		
	Coordinated Vulnerability Disclosure: Does the			
500.0	manufacturer have a vulnerability disclosure program			
DOC-8	for this device?	Yes		
	ISAO: Is the manufacturer part of an Information			
DOC-9	Sharing and Analysis Organization?	Yes		
	Diagram: Is a network or data flow diagram available			
	that indicates connections to other system			
DOC-10	components or expected external resources?	Yes		
	SaMD: Is the device Software as a Medical Device (i.e.			
DOC-11 DOC-11.1	software-only, no hardware)?	No N/A		
DOC-11.1	Does the SaMD contain an operating system? Does the SaMD rely on an owner/operator provided	N/A		
DOC 11 3	operating system?	a1/a		
DOC-11.2	Is the SaMD hosted by the manufacturer?	N/A		
DOC 11 3	is the same hosted by the manufacturer:	ai /a		
DOC-11.3 DOC-11.4	Is the SaMD hosted by the customer?	N/A		
500 11.7	is the same notice by the customer:			
		Yes, No,		
		N/A, or		
		See Note	Note #	
	MANAGEMENT OF PERSONALLY IDENTIFIABLE			
	INFORMATION			
	Can this device display, transmit, store, or modify			
1100 4	personally identifiable information (e.g. electronic			
MPII-1	Protected Health Information (ePHI))?	See Notes	Note 1	
MPII-2	Does the device maintain personally identifiable information?	See Notes	Note 2	
	Does the device maintain personally identifiable			
	information temporarily in volatile memory (i.e., until			
MPII-2.1	cleared by power-off or reset)?	See Notes	Note 3	
	Does the device store personally identifiable			
MPII-2.2	information persistently on internal media?	See Notes	Note 4	
MDU 2 2	Is personally identifiable information preserved in the		Nete F	
MPII-2.3	device's non-volatile memory until explicitly erased?	See Notes	Note 5	
MPII-2.4	Does the device store personally identifiable information in a database?	See Notes	Note 6	
11 4.7				
	Does the device allow configuration to automatically			
	delete local personally identifiable information after			
MPII-2.5	it is stored to a long term solution?	See Notes	Note 7	
11.11.2.3	וויז זנטיבע נט מוטווצ נבווו זטוענוטווי		note /	

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
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	Does the device import/export personally identifiable		
	information with other systems (e.g., a wearable monitoring device might export personally		
MPII-2.6	identifiable information to a server)?	See Notes	Note 8
	Does the device maintain personally identifiable		
	information when powered off, or during power		
MPII-2.7	service interruptions? Does the device allow the internal media to be	See Notes	Note 9
	removed by a service technician (e.g., for separate		
MPII-2.8	destruction or customer retention)?	Yes	
	Does the device allow personally identifiable		
	information records be stored in a separate location		
	from the device's operating system (i.e. secondary internal drive, alternate drive partition, or remote		
MPII-2.9	storage location)?	See Notes	Note 10
	Does the device have mechanisms used for the		
MDU 2	transmitting, importing/exporting of personally	Con Nation	Note 11
MPII-3	identifiable information? Does the device display personally identifiable	See Notes	Note 11
MPII-3.1	information (e.g., video display, etc.)?	See Notes	Note 12
	Does the device generate hardcopy reports or images		
MPII-3.2	containing personally identifiable information?	See Notes	Note 13
	Does the device retrieve personally identifiable		
	information from or record personally identifiable		
	information to removable media (e.g., removable-		
MPII-3.3	HDD, USB memory, DVD-R/RW,CD-R/RW, tape, CF/SD card, memory stick, etc.)?	See Notes	Note 14
1411-3.3	Does the device transmit/receive or import/export		1010 14
	personally identifiable information via dedicated		
	cable connection (e.g., RS-232, RS-423, USB, FireWire,		
MPII-3.4	etc.)?	See Notes	Note 15
	Does the device transmit/receive personally identifiable information via a wired network		
MPII-3.5	connection (e.g., RJ45, fiber optic, etc.)?	See Notes	Note 16
	Does the device transmit/receive personally		
	identifiable information via a wireless network		
MPII-3.6	connection (e.g., WiFi, Bluetooth, NFC, infrared, cellular, etc.)?	See Notes	Note 17
14111 3.0	Does the device transmit/receive personally		
	identifiable information over an external network		
MPII-3.7	(e.g., Internet)?	No	
MPII-3.8	Does the device import personally identifiable information via scanning a document?	No	
INFII-5.8			
	Does the device transmit/receive personally		
MPII-3.9	identifiable information via a proprietary protocol?	No	
	Does the device use any other mechanism to transmit, import or export personally identifiable		
MPII-3.10	information?	No	
Management of Private Dat	a notes:		
	AUTOMATIC LOGOFF (ALOF) The device's ability to prevent access and misuse by		
	unauthorized users if device is left idle for a period of		
	time.		
	Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of		
	inactivity (e.g., auto-logoff, session lock, password		
ALOF-1	protected screen saver)?	Yes	
ALOE-2	Is the length of inactivity time before auto-	Voc	
ALOF-2	logoff/screen lock user or administrator configurable?		
	AUDIT CONTROLS (AUDT)		
	The ability to reliably audit activity on the device.		
	Can the medical device create additional audit last		
AUDT-1	Can the medical device create additional audit logs or reports beyond standard operating system logs?	Yes	
AUDT-1.1	Does the audit log record a USER ID?	Yes	
	Does other personally identifiable information exist in		
AUDT-1.2	the audit trail?	Yes	
	Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the		
AUDT-2	audit log:	Yes	
AUDT-2.1	Successful login/logout attempts?	Yes	
AUDT-2.2	Unsuccessful login/logout attempts?	Yes	
AUDT-2.3 AUDT-2.4	Modification of user privileges? Creation/modification/deletion of users?	Yes Vec	
AUD1-2.4	creationy mounicationy deletion of users?	Yes	
AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	No	
AUDT-2.6	Creation/modification/deletion of data?	Yes	
AUDT-2.7	Import/export of data from removable media (e.g.	Y	
ALUM-277	USB drive, external hard drive, DVD)?	Yes	

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	Receipt/transmission of data or commands over a		
AUDT-2.8 AUDT-2.8.1	network or point-to-point connection? Remote or on-site support?	Yes No	
AUD1-2.8.1	Application Programming Interface (API) and similar	NO	<u> </u>
AUDT-2.8.2	activity?	No	
AUDT-2.9	Emergency access?	No	
AUDT-2.10	Other events (e.g., software updates)?	Yes	
AUDT-2.11	Is the audit capability documented in more detail?	Yes	
	Can the owner/operator define or select which		
AUDT-3	events are recorded in the audit log? Is a list of data attributes that are captured in the	No	
AUDT-4	audit log for an event available?	No	
AUDT-4.1	Does the audit log record date/time?	Yes	
	Can date and time be synchronized by Network Time		
AUDT-4.1.1	Protocol (NTP) or equivalent time source?	No	
AUDT-5	Can audit log content be exported?	Yes	
AUDT-5.1	Via physical media? Via IHE Audit Trail and Node Authentication (ATNA)	Yes	
AUDT-5.2	profile to SIEM?	No	
	Via Other communications (e.g., external service		
AUDT-5.3	device, mobile applications)? Are audit logs encrypted in transit or on storage	No	
AUDT-5.4	media?	No	
	Can audit logs be monitored/reviewed by		
AUDT-6 AUDT-7	owner/operator? Are audit logs protected from modification?	Yes	
AUDI-7 AUDT-7.1	Are audit logs protected from modification? Are audit logs protected from access?	Yes Yes	
AUDT-8	Can audit logs be analyzed by the device?	No	
	AUTHORIZATION (AUTH)		
	The ability of the device to determine the		
	authorization of users.		
	Does the device prevent access to unauthorized users		
AUTH-1	through user login requirements or other mechanism?	See Notes	Note 18
	Can the device be configured to use federated		
	credentials management of users for authorization		
AUTH-1.1	(e.g., LDAP, OAuth)? Can the customer push group policies to the device	See Notes	Note 19
AUTH-1.2	(e.g., Active Directory)?	No	
	Are any special groups, organizational units, or group		
AUTH-1.3	policies required? Can users be assigned different privilege levels based	No	<u> </u>
	on 'role' (e.g., user, administrator, and/or service,		
AUTH-2	etc.)?	See Notes	Note 20
	Can the device owner/operator grant themselves		
	unrestricted administrative privileges (e.g., access		
	operating system or application via local root or		
AUTH-3	administrator account)? Does the device authorize or control all API access	See Notes	Note 21
AUTH-4	requests?	Yes	
	Does the device run in a restricted access mode, or		
AUTH-5	'kiosk mode', by default?	Yes	
	CYBER SECURITY PRODUCT UPGRADES (CSUP)		
	The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade		
	device's security patches.		
	Does the device contain any software or firmware		
	which may require security updates during its operational life, either from the device manufacturer		
	or from a third-party manufacturer of the		
	software/firmware? If no, answer "N/A" to questions		
CSUP-1	in this section. Does the device contain an Operating System? If yes,	Yes	-
CSUP-2	complete 2.1-2.4.	Yes	
	Does the device documentation provide instructions		
CSUP-2.1	for owner/operator installation of patches or software updates?	See Notes	Note 22
	Does the device require vendor or vendor-authorized		
CSUP-2.2	service to install patches or software updates?	No	
	Does the device have the capability to receive remote		
CSUP-2.3	installation of patches or software updates?	No	_
	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g.,		
	Microsoft) to be installed without approval from the		
CSUP-2.4	manufacturer?	See Notes	Note 23
	manufacturer? Does the device contain Drivers and Firmware? If yes,		Note 23
CSUP-2.4 CSUP-3	manufacturer?	See Notes Yes	Note 23
	manufacturer? Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.		Note 23

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CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	See Notes	Note 24
	Does the device have the capability to receive remote		
CSUP-3.3	installation of patches or software updates?	No	
	Does the medical device manufacturer allow security		
	updates from any third-party manufacturers (e.g.,		
CSUP-3.4	Microsoft) to be installed without approval from the manufacturer?	See Notes	Note 25
C30P-3.4	Does the device contain Anti-Malware Software? If	See Notes	Note 25
CSUP-4	yes, complete 4.1-4.4.	Yes	
	Does the device documentation provide instructions		
C(1)D 4 4	for owner/operator installation of patches or		
CSUP-4.1	software updates?	See Notes	Note 26
	Does the device require vendor or vendor-authorized		
CSUP-4.2	service to install patches or software updates?	No	
CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	No	
	Does the medical device manufacturer allow security		
	updates from any third-party manufacturers (e.g.,		
	Microsoft) to be installed without approval from the		
CSUP-4.4	manufacturer?	See Notes	Note 27
	Does the device contain Non-Operating System commercial off-the-shelf components? If yes,		
CSUP-5	complete 5.1-5.4.	Yes	
	Does the device documentation provide instructions		
	for owner/operator installation of patches or	No	
CSUP-5.1	software updates?	No	
	Does the device require vendor or vendor-authorized		
CSUP-5.2	service to install patches or software updates?	Yes	
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	No	
C30P-5.5	Does the medical device manufacturer allow security		
	updates from any third-party manufacturers (e.g.,		
	Microsoft) to be installed without approval from the		
CSUP-5.4	manufacturer?	No	
	Does the device contain other software components		
	(e.g., asset management software, license		
	management)? If yes, please provide details or		
CSUP-6	reference in notes and complete 6.1-6.4.	No	
	Does the device documentation provide instructions		
CSUP-6.1	for owner/operator installation of patches or software updates?	N/A	
	Does the device require vendor or vendor-authorized		
CSUP-6.2	service to install patches or software updates?	N/A	
	Does the device have the capability to receive remote		
CSUP-6.3	installation of patches or software updates?	N/A	
	Does the medical device manufacturer allow security		
	updates from any third-party manufacturers (e.g.,		
CSUP-6.4	Microsoft) to be installed without approval from the manufacturer?	N/A	
	Does the manufacturer notify the customer when		
CSUP-7	updates are approved for installation?	Yes	
6511D 0	Does the device perform automatic installation of		
CSUP-8	software updates?	No	
	Does the manufacturer have an approved list of third-		
CSUP-9	party software that can be installed on the device?	No	
	Can the owner/operator install manufacturer-		
CEUD 10	approved third-party software on the device	N/A	
CSUP-10	themselves? Does the system have mechanism in place to prevent	N/A	
CSUP-10.1	installation of unapproved software?	N/A	
	Does the manufacturer have a process in place to		
CSUP-11	assess device vulnerabilities and updates?	Yes	
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	No	
CSUP-11.2	Is there an update review cycle for the device?	Yes	
	gue los ale denices		
	HEALTH DATA DE-IDENTIFICATION (DIDT)		
	The ability of the device to directly remove		
	information that allows identification of a person.		
	Does the device provide an integral approximity to the		
DIDT-1	Does the device provide an integral capability to de- identify personally identifiable information?	See Notes	Note 28
	Does the device support de-identification profiles		
	that comply with the DICOM standard for de-		
DIDT-1.1	identification?	N/A	

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
	DATA BACKUP AND DISASTER RECOVERY (DTBK) The ability to recover after damage or destruction of		
	device data, hardware, software, or site		
	configuration information.		
	Does the device maintain long term primary storage of personally identifiable information / patient		
DTBK-1	information (e.g. PACS)?	See Notes	Note 29
	Does the device have a "factory reset" function to restore the original device settings as provided by the		
DTBK-2	manufacturer?	Yes	
DTBK-3	Does the device have an integral data backup capability to removable media?	Yes	
	Does the device have an integral data backup		
DTBK-4	capability to remote storage? Does the device have a backup capability for system	Yes	
	configuration information, patch restoration, and		
DTBK-5	software restoration?	No	
	Does the device provide the capability to check the		
DTBK-6	integrity and authenticity of a backup?	Yes	
	EMERGENCY ACCESS (EMRG)		
	The ability of the device user to access personally		
	identifiable information in case of a medical		
	emergency situation that requires immediate access to stored personally identifiable information.		
	Does the device incorporate an emergency access		
EMRG-1	(i.e. "break-glass") feature?	No	
	HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)		
	How the device ensures that the stored data on the		
	device has not been altered or destroyed in a non- authorized manner and is from the originator.		
	Does the device provide data integrity checking		
IGAU-1	mechanisms of stored health data (e.g., hash or digital signature)?	No	
	Does the device provide error/failure protection and		
IGAU-2	recovery mechanisms for stored health data (e.g., RAID-5)?	No	
	MALWARE DETECTION/PROTECTION (MLDP)		
	The ability of the device to effectively prevent, detect		
	and remove malicious software (malware).		
MLDP-1	Is the device canable of besting executable software?	Vac	
WILDT-1	Is the device capable of hosting executable software?		
	Does the device support the use of anti-malware		
MLDP-2	software (or other anti-malware mechanism)? Provide details or reference in notes.	Yes	
	Does the device include anti-malware software by		
MLDP-2.1	default? Does the device have anti-malware software	Yes	
MLDP-2.2	available as an option?	No	
	Does the device documentation allow the owner/operator to install or update anti-malware		
MLDP-2.3	software?	No	
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	No	
	Does notification of malware detection occur in the		
MLDP-2.5	device user interface?	No	
	Can only manufacturer-authorized persons repair		
MLDP-2.6 MLDP-2.7	systems when malware has been detected? Are malware notifications written to a log?	See Notes See Notes	Note 30 Note 31
WILDT -2.7			Note 31
	Are there any restrictions on anti-malware (e.g.,	Var	
MLDP-2.8	purchase, installation, configuration, scheduling)?	Yes	
	If the answer to MLDP-2 is NO, and anti-malware		
MLDP-3	cannot be installed on the device, are other compensating controls in place or available?	N/A	
MLDP-3	cannot be installed on the device, are other compensating controls in place or available?	N/A	
MLDP-3	cannot be installed on the device, are other	N/A	
MLDP-3 MLDP-4	cannot be installed on the device, are other compensating controls in place or available? Does the device employ application whitelisting that	N/A	

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	Can the host-based intrusion detection/prevention		
MLDP-5.1	system be configured by the customer?	N/A	
	Can a host-based intrusion detection/prevention		
MLDP-5.2	system be installed by the customer?	See Notes	Note 32
	NODE AUTHENTICATION (NAUT)		
	The ability of the device to authenticate		
	communication partners/nodes.		
	Does the device provide/support any means of node		
	authentication that assures both the sender and the		
	recipient of data are known to each other and are authorized to receive transferred information (e.g.		
NAUT-1	Web APIs, SMTP, SNMP)?	No	_
	Are network access control mechanisms supported		
	(E.g., does the device have an internal firewall, or use		
NAUT-2	a network connection white list)?	Yes	
NAUT-2.1	Is the firewall ruleset documented and available for review?	No	
	Does the device use certificate-based network		
NAUT-3	connection authentication?	See Notes	Note 33
	CONNECTIVITY CAPABILITIES (CONN)		
	All network and removable media connections must		
	be considered in determining appropriate security controls. This section lists connectivity capabilities		
	that may be present on the device.		
CONN 1	Does the device have hardware connectivity	San Notar	Noto 24
CONN-1 CONN-1.1	capabilities? Does the device support wireless connections?	See Notes Yes	Note 34
CONN-1.1.1	Does the device support Wi-Fi?	Yes	
CONN-1.1.2	Does the device support Bluetooth?	No	
	Does the device support other wireless network		
CONN-1.1.3	connectivity (e.g. LTE, Zigbee, proprietary)?	No	_
	Does the device support other wireless connections		
CONN-1.1.4	(e.g., custom RF controls, wireless detectors)?	No	_
CONN-1.2	Does the device support physical connections?	Yes	
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	Yes	
CONN-1.2.2	Does the device have available USB ports?	See Notes	Note 35
CONN-1.2.3	Does the device require, use, or support removable memory devices?	See Notes	Note 36
CONN-1.2.4	Does the device support other physical connectivity? Does the manufacturer provide a list of network ports	No	
	and protocols that are used or may be used on the		
CONN-2	device?	No	
CONN-3	Can the device communicate with other systems within the customer environment?	See Notes	Note 37
	Can the device communicate with other systems		
CONN-4	external to the customer environment (e.g., a service host)?	No	
CONN-5	Does the device make or receive API calls?	See Notes	Note 38
CONNIC	Does the device require an internet connection for its		
CONN-6	intended use? Does the device support Transport Layer Security	No	
CONN-7	(TLS)?	Yes	_
CONN-7.1	Is TLS configurable? Does the device provide operator control	No	
	functionality from a separate device (e.g.,		
CONN-8	telemedicine)?	Yes	
	PERSON AUTHENTICATION (PAUT)		
	The ability to configure the device to authenticate		
	users. Does the device support and enforce unique IDs and		
	passwords for all users and roles (including service		
PAUT-1	accounts)? Does the device enforce authentication of unique IDs	See Notes	Note 39
	and passwords for all users and roles (including		
PAUT-1.1	service accounts)?	See Notes	Note 40
	Is the device configurable to authenticate users		
	through an external authentication service (e.g., MS		
PAUT-2	Active Directory, NDS, LDAP, OAuth, etc.)?	No	
	Is the device configurable to lock out a user after a		
PAUT-3	certain number of unsuccessful logon attempts?	No	_
	Are all default accounts (e.g., technician service		
PAUT-4 PAUT-5	accounts, administrator accounts) listed in the documentation?	No Yes	

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	Is the device configurable to enforce creation of user		
	account passwords that meet established		
PAUT-6	(organization specific) complexity rules?	See Notes	Note 41
PAUT-7	Does the device support account passwords that expire periodically?	No	
PAUT-8 PAUT-9	Does the device support multi-factor authentication? Does the device support single sign-on (SSO)?	No No	
PA01-9	Does the device support single sign-on (SSO)?		
PAUT-10	Can user accounts be disabled/locked on the device?	No	_
PAUT-11	Does the device support biometric controls? Does the device support physical tokens (e.g. badge	No	
PAUT-12	access)?	See Notes	Note 42
2417.42	Does the device support group authentication (e.g.		
PAUT-13	hospital teams)? Does the application or device store or manage	No	
PAUT-14	authentication credentials?	Yes	_
PAUT-14.1	Are credentials stored using a secure method?	Yes	
	PHYSICAL LOCKS (PLOK)		
	Physical locks can prevent unauthorized users with		
	physical access to the device from compromising the integrity and confidentiality of personally identifiable		
	information stored on the device or on removable		
	media Is the device software only? If yes, answer "N/A" to		
PLOK-1	remaining questions in this section.	No	
	Are all device components maintaining personally		
	identifiable information (other than removable media) physically secure (i.e., cannot remove without		
PLOK-2	tools)?	See Notes	Note 43
	Are all device components maintaining personally identifiable information (other than removable		
	media) physically secured behind an individually		
PLOK-3	keyed locking device?	See Notes	Note 44
	Does the device have an option for the customer to attach a physical lock to restrict access to removable		
PLOK-4	media?	No	
	ROADMAP FOR THIRD PARTY COMPONENTS IN		
	DEVICE LIFE CYCLE (RDMP)		
	Manufacturer's plans for security support of third-		
	party components within the device's life cycle.		
	Was a secure software development process, such as ISO/IEC 27034 or IEC 62304, followed during product		
RDMP-1	development?	See Notes	Note 45
	Does the manufacturer evaluate third-party		
	applications and software components included in		
RDMP-2	the device for secure development practices? Does the manufacturer maintain a web page or other	Yes	
	source of information on software support dates and		
RDMP-3	updates?	Yes	
RDMP-4	Does the manufacturer have a plan for managing third-party component end-of-life?	Yes	
	SOFTWARE BILL OF MATERIALS (SBoM)		
	A Software Bill of Material (SBOM) lists all the		
	software components that are incorporated into the		
	device being described for the purpose of operational security planning by the healthcare delivery		
	organization. This section supports controls in the		
SBOM-1	RDMP section. Is the SBoM for this product available?	Vor	
	Is the SBOM for this product available? Does the SBOM follow a standard or common method	Yes	
SBOM-2	in describing software components?	Yes	
SBOM-2.1	Are the software components identified? Are the developers/manufacturers of the software	Yes	
SBOM-2.2	components identified?	Yes	
SPOM 2.2	Are the major version numbers of the software	Voc	
SBOM-2.3	components identified?	Yes	-
SBOM-2.4	Are any additional descriptive elements identified?	No	
	Does the device include a command or process method available to generate a list of software		
SBOM-3	components installed on the device?	No	
SBOM-4	Is there an update process for the SBoM?	Yes	
	SYSTEM AND APPLICATION HARDENING (SAHD)		
	The device's inherent resistance to cyber attacks and		
			1
	malware. Is the device hardened in accordance with any		

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	Has the device received any cybersecurity		
SAHD-2	certifications? Does the device employ any mechanisms for software	No	
SAHD-3	integrity checking Does the device employ any mechanism (e.g., release-	No	
	specific hash key, checksums, digital signature, etc.)		
SAHD-3.1	to ensure the installed software is manufacturer- authorized?	See Notes	Note 46
-	Does the device employ any mechanism (e.g., release-		
	specific hash key, checksums, digital signature, etc.) to ensure the software updates are the manufacturer-		
SAHD-3.2	authorized updates?	Yes	
	Can the owner/operator perform software integrity checks (i.e., verify that the system has not been		
SAHD-4	modified or tampered with)?	No	_
	Is the system configurable to allow the implementation of file-level, patient level, or other		
SAHD-5	types of access controls?	No	
SAHD-5.1	Does the device provide role-based access controls?	Yes	
	Are any system or user accounts restricted or		
SAHD-6	disabled by the manufacturer at system delivery? Are any system or user accounts configurable by the	See Notes	Note 47
SAHD-6.1	end user after initial configuration?	No	
	Does this include restricting certain system or user accounts, such as service technicians, to least		
SAHD-6.2	privileged access? Are all shared resources (e.g., file shares) which are	No	
	not required for the intended use of the device disabled?	N/A	
SAHD-7	Are all communication ports and protocols that are	N/A	
SAHD-8	not required for the intended use of the device disabled?	See Notes	Note 48
	Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which		
	are not required for the intended use of the device		
SAHD-9	deleted/disabled? Are all applications (COTS applications as well as OS-	Yes	
	included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the		
SAHD-10	device deleted/disabled?	See Notes	Note 49
	Can the device prohibit boot from uncontrolled or		
SAHD-11	removable media (i.e., a source other than an internal drive or memory component)?	No	_
	Can unauthorized software or hardware be installed		
SAHD-12	on the device without the use of physical tools?	Yes	
	Does the product documentation include information		
SAHD-13	on operational network security scanning by users? Can the device be hardened beyond the default	No	
SAHD-14	provided state? Are instructions available from vendor for increased	See Notes	Note 50
SAHD-14.1	hardening?	See Notes	Note 51
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	No	
	Have additional hardening methods not included in		
SAHD-16	2.3.19 been used to harden the device?	See Notes	Note 52
	SECURITY GUIDANCE (SGUD) Availability of security guidance for operator and		
	administrator of the device and manufacturer sales		
	and service. Does the device include security documentation for		
SGUD-1	the owner/operator? Does the device have the capability, and provide	Yes	
SGUD-2	instructions, for the permanent deletion of data from the device or media?	See Notes	Note 53
SGUD-3	Are all access accounts documented? Can the owner/operator manage password control	See Notes	Note 54
SGUD-3.1	for all accounts?	See Notes	Note 55
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	No	
	controls for the device?		
	HEALTH DATA STORAGE CONFIDENTIALITY		
	(STCF)		
	The ability of the device to ensure unauthorized		
	access does not compromise the integrity and confidentiality of personally identifiable information		
STCF-1	stored on the device or removable media.	No	
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STCF-1.1	Is all data encrypted or otherwise protected?	See Notes	Note 56
	Is the data encryption capability configured by		
STCF-1.2	default?	N/A	
STCF-1.3	Are instructions available to the customer to	a1/a	
STCF-1.3	configure encryption?	N/A	
STCF-2	Can the encryption keys be changed or configured?	N/A	
	Is the data stored in a database located on the		
STCF-3	device?	Yes	
	Is the data stored in a database external to the		
STCF-4	device?	No	
	TRANSMISSION CONFIDENTIALITY (TXCF)		
	The ability of the device to ensure the confidentiality		
	of transmitted personally identifiable information.		
	Can personally identifiable information be		
TXCF-1	transmitted only via a point-to-point dedicated cable?	No	-
	Is personally identifiable information encrypted prior		
TXCF-2	to transmission via a network or removable media?	See Notes	Note 57
	If data is not encrypted by default, can the customer		
TXCF-2.1	configure encryption options?	No	
TVCE 2	Is personally identifiable information transmission restricted to a fixed list of network destinations?	N-	
TXCF-3	restricted to a fixed list of network destinations?	No	
TXCF-4	Are connections limited to authenticated systems?	No	
	Are secure transmission methods		
TXCF-5	supported/implemented (DICOM, HL7, IEEE 11073)?	No	
	TRANSMISSION INTEGRITY (TXIG)		
	The ability of the device to ensure the integrity of transmitted data.		
	Does the device support any mechanism (e.g., digital		
	signatures) intended to ensure data is not modified		
TXIG-1	during transmission?	No	
	Does the device include multiple sub-components		
TXIG-2	connected by external cables?	No	
	REMOTE SERVICE (RMOT)		
	Remote service refers to all kinds of device		
	maintenance activities performed by a service person		
	via network or other remote connection.		
	Does the device permit remote service connections		
RMOT-1	for device analysis or repair? Does the device allow the owner/operator to	No	
	initiative remote service sessions for device analysis		
RMOT-1.1	or repair?	N/A	
	Is there an indicator for an enabled and active remote		
RMOT-1.2	session?	N/A	
	Can patient data be accessed or viewed from the		
RMOT-1.3	device during the remote session? Does the device permit or use remote service	N/A	
RMOT-2	Does the device permit or use remote service connections for predictive maintenance data?	No	
	Does the device have any other remotely accessible		
	functionality (e.g. software updates, remote		
RMOT-3	training)?	See Notes	Note 58
	OTHER SECURITY CONSIDERATIONS (OTHR)		
	NONE		
	Notes:		

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is maintained on the System. The system does have the ability to clear personally identifiable information				
the ability to clear personally identifiable information				
through a Factory Reset Feature. Note 3	Note 3	through a Factory Reset Feature.		

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
BIOFINE Diagnostics, LLC		516001 0102 01	22100202
	The following data fields are associated with each test on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, and any other unique identifying number, characteristic, or		
	code in the Sample ID field. To the extent the information contained in any these fields is personally identifiable information, as defined in ANSI/NEMA HN 1-2019, such information is stored on internal media within the System.		
Note 4			
	The following data fields are associated with each test on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, and any other unique identifying number, characteristic, or code in the Sample ID field.		
Note 5	To the extent the information contained in any these fields is personally identifiable information, as defined in ANSI/NEMA HN 1-2019, such information is preserved in the System's nonvolatile memory until explicitly erased.		
	The following data fields are associated with each test on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, and any other unique identifying number, characteristic, or code in the Sample ID field.		
Note 6	To the extent the information contained in any these fields is personally identifiable information, as defined in ANSI/NEMA HN 1-2019, such information is stored in a database within the System.		

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number,		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be deleted by the software. As an optional		
	feature, the System may be configured to transmit		
Note 7	such information.		
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	Sample Type, Fouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be imported/exported with other systems via		
	configuration of optional connectivity features.		
Note 8	The following data fields are associated with each test		
	The following data fields are associated with each test on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number,		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be maintained when powered off, or during		
	power service interruptions.		

	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
BIOFIRE Diagnostics, LLC			22-re0-202
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number,		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or code in the Sample ID field.		
	code in the sample ib field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be stored in a separate location from the		
Note 10	System's operating system.		
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number, characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, the System does		
	have mechanisms used for transmitting and		
	importing/exporting such information.		
Note 11			
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number,		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	is displayed by the System.		
Note 12			

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
	The following data fields are seen sisted with a sub-		
	The following data fields are associated with each test on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number,		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be contained on generated hard copy reports or		
Note 13	images.		
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number,		
	Sample Type, Pouch Type, and a Sample ID.		
	The "Console UP" field is a free test field and		
	The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be retrieved from or recorded to removable		
	media.		
Note 14			
	The following data fields are associated with each test		
	on the System: Run Start Time and Run End Time,		
	Serial Number (of consumable), Lot Number (of		
	consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	Sumple Type, Fouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and		
	bioMérieux issues guidance to use sequentially		
	generated recycled accession numbers in the		
	"Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic		
	information, financial		
	information, medical record numbers, Social Security		
	numbers, and any other unique identifying number,		
	characteristic, or		
	code in the Sample ID field.		
	To the extent the information contained in any these		
	fields is personally identifiable information, as		
	defined in ANSI/NEMA HN 1-2019, such information		
	may be transmitted/received or imported/exported		
	via dedicated cable connection.		
Note 15			
Note 15			

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
	The following data fields are associated with each test on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID. The "Sample ID" field is a free text field, and biolMerieux issues guidance to use sequentially generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, and any other unique identifying number, characteristic, or code in the Sample ID field. To the extent the information contained in any these fields is personally identifiable information, as defined in ANSI/NEMA HN 1-2019, such information		
Note 16	may be transmitted/received via a wired network connection.		
	The following data fields are associated with each test on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID. The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do		
	not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, and any other unique identifying number, characteristic, or code in the Sample ID field.		
Note 17	To the extent the information contained in any these fields is personally identifiable information, as defined in ANSI/NEMA HN 1-2019, such information may be transmitted/received over an external network if the System is configured with an optional connectivity feature.		
	The System is pre-configured to log on to Windows using the SPOTFIRE user account automatically. The SPOTFIRE user account is a Windows Standard User with its equivalent access rights.		
	The System computer is also pre-configured with an administrative user account (LabAdmin). It is recommended the System owner/operator change the default password for the LabAdmin user account as the account has local administrative privileges. SPOTFIRE has a set operator list which only allows the		
Note 18	SPOTFIRE application software to be accessed.		
	When optional connectivity features are enabled, application user credentials may be maintained by a centralized data-management system and distributed over a network to one or multiple connected devices according to the customer's organizational requirements. In this configuration, application user credentials on the device cannot be modified or shared with other devices.		
Note 19	The system allows operators to be created with or		
Note 20	without administrator privileges. The System is operated using a Windows Operating System User Account that does not have administrative privileges. Configuration changes require administrative privileges using an administrative Windows user account pre-configured on the computer. The System application software does not allow construct to medify this use administrators		
Note 21	operators to modify their own administrator <u>privileges</u> . Instructions for the owner/operator installation of Operating System patches are within BFR0001-6037 Microsoft OS Patch Policy Tech Note.		
Note 22	Instructions for the owner/operator installation of Operating System patches are within BFR0001-6037 Microsoft OS Patch Policy Tech Note.		
Note 23			

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
Note 24	Documentation for Driver and Firmware patches or updates, if required, will be distributed by bioMérieux's BIOFIRE Technical Support team.		
	The recommended installation process for updates from third party manufactures (e.g. Microsoft) is available within BFR0001-6037 Microsoft OS Patch Policy Tech Note.		
Note 25	Instructions for the owner/operator installation of		
Note 26	AntiMalware Software patches are within BFR0001- 6037 Microsoft OS Patch Policy Tech Note.		
Note 27	The recommended installation process for updates from third party manufactures (e.g. Microsoft) is available within BFR0001-6037 Microsoft OS Patch Policy Tech Note.		
	The following data fields are associated with each test on the System: Run Start Time and Run End Time, Serial Number (of consumable), Lot Number (of consumable), Operator, Module Serial Number, Sample Type, Pouch Type, and a Sample ID.		
	The "Sample ID" field is a free text field, and bioMérieux issues guidance to use sequentially generated recycled accession numbers in the "Sample ID" field. Consistent with this guidance, do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social		
	Security numbers, and any other unique identifying number, characteristic, or code in the Sample ID field. To the extent the information contained in any these fields is personally identifiable information, as defined in ANSI/NEMA HN 1-2019, the System has the capability to remove such		
N=t= 20	information upon export.		
Note 28	The System is not intended to maintain long term primary storage of data. See the System Operator's Manual for data archiving guidance.		
Note 29	If a System is believed to be impacted by malware, please contact the BIOFIRE Technical Support team for assistance.		
Note 30	Operating system and security event auditing utilizes		
Note 31	Windows logging features. Installation and maintenance of antivirus, intrusion detection, and other detection/prevention systems is the responsibility of the end user.		
Note 32	Certificate-based network connection authentication may be utilized through the Windows Operating		
Note 33	System. Reference the System Operator's Manual for the System's hardware connectivity capabilities.		
Note 34	Reference the System Operator's Manual for details		
Note 35	on the System's available USB ports. Reference the System Operator's Manual for details on the System's capability to use or support		
Note 36	removable memory devices. If optional connectivity features are enabled, the System may communicate with other systems within the customer environment but does not communicate with other SPOTFIRE Systems.		
Note 37			
Note 38	The System only makes internal API calls. Device operation requires all users to authenticate with a unique user ID/password combination or barcode number maintained through the application software. Windows user accounts may be separately used to access to the operating system, as follows: - Windows administrator-level accounts require authentication with a unique user ID/password combination - Windows user-level account requires a unique user		
Noto 29	ID only (no password)		
Note 39	Device operation requires all users to authenticate with a unique user ID/password combination or barcode number maintained through the application software. Windows user accounts may be separately used to access to the operating system, as follows: - Windows administrator-level accounts require authentication with a unique user ID/password		
Note 40	combination - Windows user-level account requires a unique user ID only (no password)		

BIOFIRE Diagnostics, LLC	BIOFIRE® SPOTFIRE® SYSTEM	BFR0001-8102-01	22-Feb-2023
	The system application software (SPOTFIRE) enforces		
	user account passwords that meet established		
	complexity rules.		
	The Windows administrator-level accounts do not		
	enforce user account passwords that meet		
Note 41	established complexity rules.		
	The system application software (SPOTFIRE) allows an admin operator to optionally enable barcode badge		
	access which can be used by all operators. When		
	enabled, all operators can associate a unique barcode		
	that can be used for their authentication.		
Note 42	To the extent that the System maintains personally		
	identifiable information, such information is		
	physically secure. (See Note 2 for additional		
	information on the System's ability to maintain		
Note 43	patient identifiable information)		
	To the extent that the System maintains personally		
	identifiable information, such information is		
	physically secure, but is not behind an individually keyed locking device. (See Note 2 for additional		
	information on the System's ability to maintain		
	patient identifiable information)		
Note 44	The software was developed in accordance with 150		
Note 45	The software was developed in accordance with IEC 62304.		
	Quality Assurance processes conducted during the		
Noto 46	System's assembly ensure the installed software is		
Note 46	manufacturer authorized. The Microsoft Windows Operating System		
Note 47	"BMX_Guest" account is disabled by default.		
	The System is configured to block inbound connection		
	requests on all network ports. However, if optional		
	connectivity features are enabled, outbound connections are allowed on any available network		
	port (1-65535). No port exclusions are currently		
Note 48	configured.		
	The system uses a modified Windows 10 IoT Enterprise 2019 LTSC Version 1809 image which		
	includes deleting and/or disabling many features that		
	are not required for the intended use of the device.		
Note 49	16		
	If you have any questions or concerns about system hardening beyond the default state, please contact		
	the BIOFIRE Technical Support team for assistance.		
Note 50	15		
	If you have any questions or concerns about system hardening beyond the default state, please contact		
	the BIOFIRE Technical Support team for assistance.		
Note 51			
	Department of Defense's Security Technical		
	Implementation Guides have been used to harden the Microsoft Windows Operating System.		
Note 52			
	The SPOTFIRE application software has a Factory		
Note 53	Reset feature that will remove all data from the system.		
	Windows operating system accounts are not		
	documented. SPOTFIRE application software role-		
Note 54	based access accounts are documented in the Operators Manual.		
	The SPOTFIRE application software allows admin		
	operators to manage password control. The		
	SPOTFIRE application software cannot make changes		
	directly to the Windows OS accounts. If the 'Switch to Windows OS' is used the owner then has access to		
	manage password control for the Windows accounts.		
Note 55			
	Data protection mechanisms in place on the system include password protection of the local databases,		
	anonymization of the run data when exporting		
	anonymously, the use of API keys protecting our		
Noto F6	services, and data bundle creation.		
Note 56	Data is encrypted prior to transmission via removable		
	media. If the System's optional connectivity features		
	are enabled, data is not encrypted prior to		
	transmission through the optional connectivity		
Note 57	features, the removable media encryption remains the same.		
	If optional connectivity features are enabled,		
No. 50	operator profiles and software settings can be		
Note 58	remotely configured.		