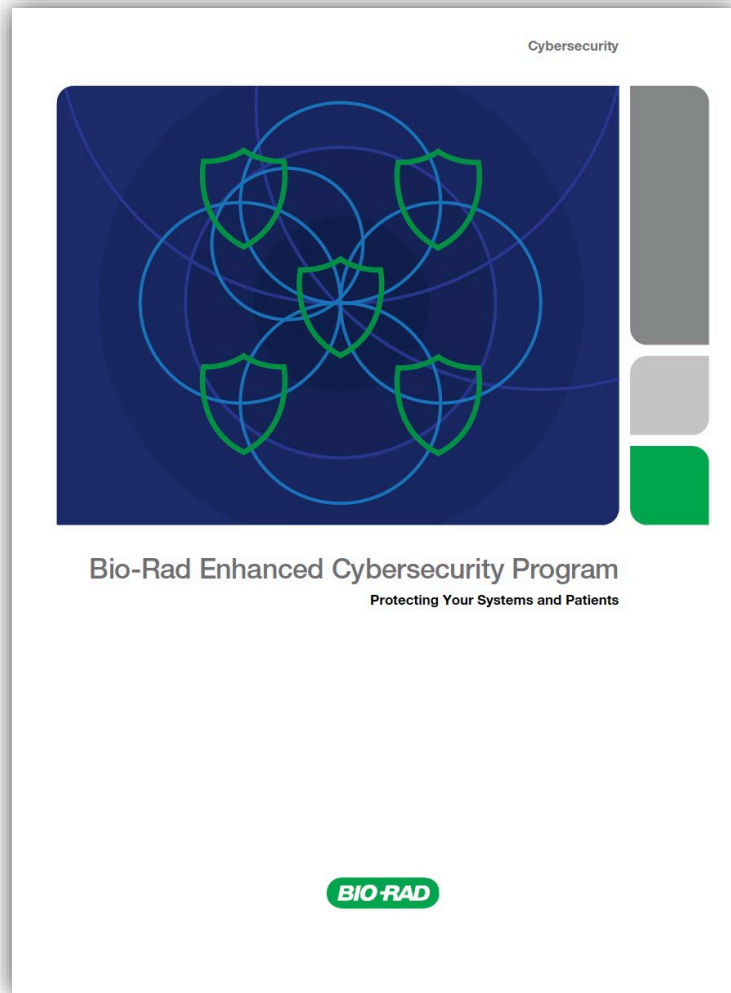




# Bio-Rad ECP Publication Guide

December, 2020



## Publication Guide

Bio-Rad Enhanced Cybersecurity Program

*REF: DG20-1296 Z-1014*

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Use this publication to:

- Highlight the importance of cybersecurity in clinical diagnostics
- Discuss the cybersecurity solutions that Bio-Rad has implemented
- Demonstrate how Bio-Rad is protecting systems and patients
- Reassure the benefits of connectivity despite cybersecurity threats
- Support tender/RFP submissions

# “Prevention is better than cure”



## Global Costs \$8 Billion

NHS (UK) – The WannaCry ransomware cyber attack in 2017 cost the National Health Service almost £100m and led to the cancellation of 19,000 appointments



## “Prevention is better than cure”

- A cyber incident can have a financial impact
- Patient outcomes can be influenced by malicious attacks
- Preventing against cyber attacks allows critical services to be maintained
- Bio-Rad is implementing measures to protect services and patients

## 2. Cybersecurity by Design

The Bio-Rad Cybersecurity Program has adopted a “Cybersecurity by Design” approach to ensure that security measures are being integrated into each stage of our product lifecycle management. We know that clinical diagnostic systems, routinely connected with hospital networks, other medical devices, and the internet, are fundamental in improving laboratory workflow and supporting better patient care. With more connectivity there is an increasing vulnerability to cybersecurity breaches which can potentially disrupt the delivery of critical services. As a trusted manufacturer and supplier of medical devices and services, Bio-Rad is committed to working together with you and your lab to mitigate against potential cybersecurity risks.

### FOCUS POINTS

- New product design / software updates now involves the introduction of features/functions related specifically to cybersecurity e.g. user level access, anonymisation of sensitive patient data, password complexity
- International standards have been introduced specific to information security management (ISO 27001) and cybersecurity protection methods (IEC 62443)
- The benefits of connectivity need to be protected
- This is not a one sided approach – it requires a hand in hand partnership for success
- [THE FDA'S ROLE IN MEDICAL DEVICE CYBERSECURITY](#) ➔

**1**

### An Enhanced Approach to Product Cybersecurity

Bio-Rad is committed to working with hospitals and laboratories to protect your systems and mitigate potential security risks to patients and operators

Digital threats, including viruses, malware, and malicious code can be a threat to the integrity of patient results, treatment, and privacy. As online attacks grow, it becomes more important than ever for Bio-Rad to proactively defend your systems. Bio-Rad's approach to cybersecurity utilizes the latest thinking in diagnostic system defenses to create a digital barricade against online threats.

**2**

### Cybersecurity by Design

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### More than ever we need vigilance

The healthcare industry is a prime target for cybercriminals looking to exploit vulnerabilities in systems and devices. Sophisticated measures are being employed to prevent data breaches and malicious attacks. Rest assured, we've placed cybersecurity at the forefront of our efforts to maintain critical services and protect patients. Our Product Cybersecurity Center of Excellence helps manage and lead all aspects of the Cybersecurity Program.

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### FOCUS POINTS

- Cyber attacks are on the increase
- Bio-Rad is taking a proactive approach

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### FOCUS POINTS

- Bio-Rad have firsthand experience in dealing with cybersecurity incidents
- Bio-Rad have established a team of experts (PCCoE) to coordinate a global approach against an evolving threat

# Inside right (1)

1. Bio-Rad utilizes an **interconnected approach** to maximize the protection of your diagnostic systems

## FOCUS POINTS

- There is not a single product which can be used to protect against all malicious threats
- The five shields are Bio-Rad's interconnected defense working together to provide an enhanced approach

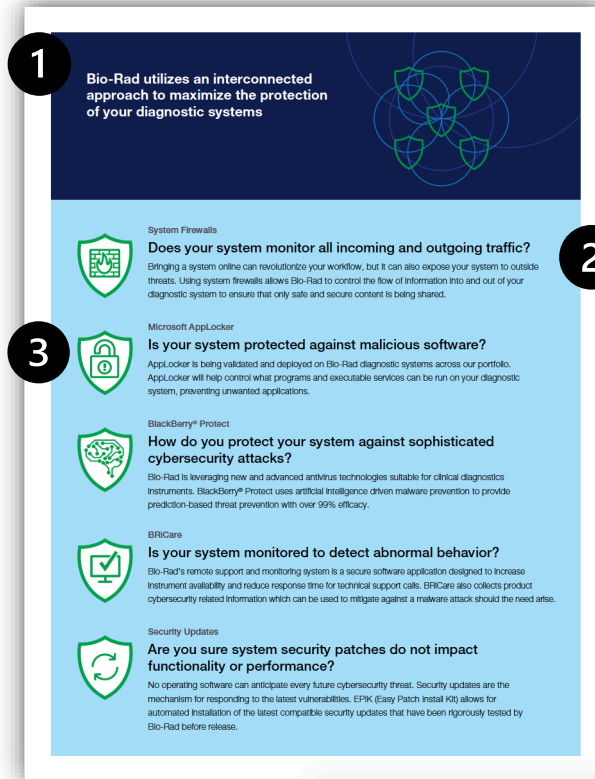
3. Microsoft AppLocker

Is your system protected against malicious software?

**AppLocker is being validated and deployed on Bio-Rad diagnostic systems across our portfolio.** AppLocker will help control what programs and executable services can be run on your diagnostic system, preventing unwanted applications.

## FOCUS POINTS

- AppLocker allows only the applications approved by Bio-Rad to be run on our systems
- If an application is not on a "whitelist" - it cannot be executed
- AppLocker is validated for use on Bio-Rad systems and is free of charge for our customers



**1** Bio-Rad utilizes an interconnected approach to maximize the protection of your diagnostic systems

**2** System Firewalls  
Does your system monitor all incoming and outgoing traffic?  
Bringing a system online can revolutionize your workflow, but it can also expose your system to outside threats. Using system firewalls allows Bio-Rad to control the flow of information into and out of your diagnostic system to ensure that only safe and secure content is being shared.

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BlackBerry® Protect  
How do you protect your system against sophisticated cybersecurity attacks?  
Bio-Rad is leveraging new and advanced antivirus technologies suitable for clinical diagnostics instruments. BlackBerry® Protect uses artificial intelligence driven malware prevention to provide prediction-based threat prevention with over 99% efficacy.

BRICare  
Is your system monitored to detect abnormal behavior?  
Bio-Rad's remote support and monitoring system is a secure software application designed to increase instrument availability and reduce response time for technical support calls. BRICare also collects product cybersecurity related information which can be used to mitigate against a malware attack should the need arise.

Security Updates  
Are you sure system security patches do not impact functionality or performance?  
No operating software can anticipate every future cybersecurity threat. Security updates are the mechanism for responding to the latest vulnerabilities. EPK (Easy Patch Install Kit) allows for automated installation of the latest compatible security updates that have been rigorously tested by Bio-Rad before release.

2. System Firewalls

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## FOCUS POINTS

- Firewalls are the first shield – rules are configured by Bio-Rad during manufacturing to ensure the safe operation of systems when they are connected to the laboratory network

# Inside right (2)

## 4. BlackBerry® Protect

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### FOCUS POINTS

- BlackBerry® Protect is an optional anti-malware solution
- BlackBerry® Protect is a licensed (invoiced) product
- It is validated for use with Bio-Rad Systems
- No other third party anti-malware is approved for use on Bio-Rad systems
- It does not require an internet connection to function
- BlackBerry® Protect allows the routine processing of patient samples without impacting system performance
- [Bio-Rad Premium Cybersecurity Offering](#)
- [Secure IoT in Healthcare](#)

## 5. BRiCare

### Is your system monitored to detect abnormal behavior?

Bio-Rad's remote support and monitoring system is a secure software application designed to increase instrument availability and reduce response time for technical support calls. BRiCare also collects product cybersecurity related information which can be used to mitigate against a malware attack should the need arise.

### FOCUS POINTS

- BRiCare functionality has been extended to collect data related to cybersecurity e.g. latest security updates installed
- Patient data is not collected
- In case of a cybersecurity incident, BRiCare could be used to help recover the system to operation
- BRiCare is secure and free of charge for Bio-Rad customers

Bio-Rad utilizes an interconnected approach to maximize the protection of your diagnostic systems

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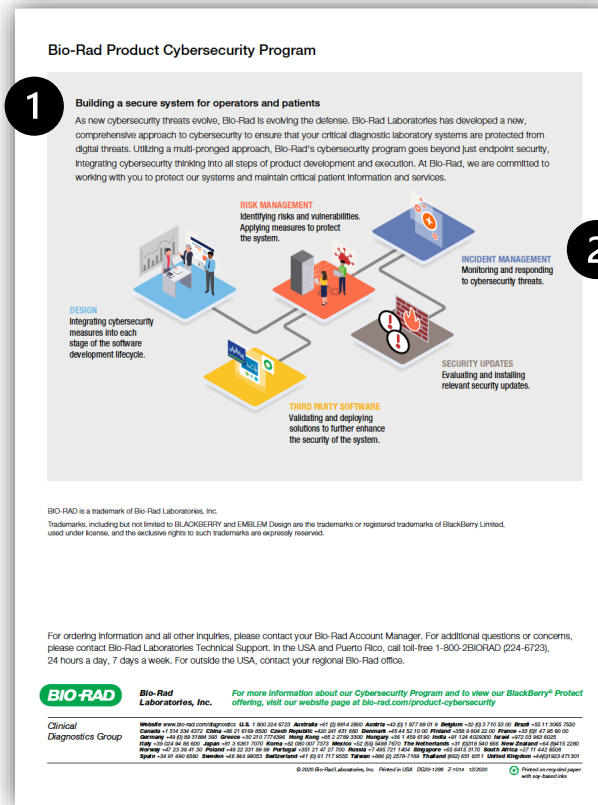
- Bio-Rad does not recommend automatic updates to be enabled
- Operating System updates can affect instrument functionality and performance
- By validating security updates before release, Bio-Rad can ensure that instrument operation is not negatively impacted after installation
- EPIK is a tool developed by the Bio-Rad PCCoE that automates the process of Microsoft security updates relevant for Bio-Rad systems

## 1. Building a secure system for operators and patients

As new cybersecurity threats evolve, Bio-Rad is evolving the defense. Bio-Rad Laboratories has developed a new, comprehensive approach to cybersecurity to ensure that your critical diagnostic laboratory systems are protected from digital threats. Utilizing a multi-pronged approach, Bio-Rad's cybersecurity program goes beyond just endpoint security, integrating cybersecurity thinking into all steps of product development and execution. At Bio-Rad, we are committed to working with you to protect our systems and maintain critical patient information and services.

### FOCUS POINTS

- Cybersecurity thinking – this is a dynamic and changing threat which requires the matching of best practices and products
- Bio-Rad is innovating not only in providing the best products for clinical laboratories but also in protecting these critical services
- This is and will remain a partnership with our customers against a common threat.



## 2. Infographic

### FOCUS POINTS

- Represents the pillars of Bio-Rad's Cybersecurity Program
- These are based upon recommendations and regulations for manufacturers of medical devices
- The shields are the defense in the battle, the program is the strategy in the war against Cybersecurity threats
- [Product Cybersecurity Position Paper](#)