6th November 2024

URGENT: FIELD SAFETY NOTICE – IDS-25-5176

Product Cybersecurity

REF: See Table 1

Type of Action: Field Work

Attention: Laboratory Managers, Risk Managers, IT Managers

This letter contains important information which requires your **immediate** attention.

Dear customer,

BD is issuing a Field Safety Corrective Action for the products listed in the impacted product Table 1. According to our distribution records your organisation may have an installation of one or more of the products listed in Table 1.

Product Name	Product Code (REF)	UDI	Manufacturer's SRN
BD BACTEC™ Blood Culture System	441385	00382904413859	US-MF-000018910
	445475	00382904454753	
	442296	00382904422967	
BD Phoenix™ M50 Automated Microbiology System	443624	00382904436247	
BD MAX™ System	441916	00382904419165	
BD COR™ System	443988	00382904439880	
	443989	00382904439897	
	443990	00382904439903	
BD EpiCenter™ Microbiology Data Management System	441007	00382904410070	*N/A*
	440887	00382904408879	
	440981	00382904409814	
BD Synapsys™ Informatics Solution	444150	00382904441500	

Table 1: Impacted product

Description of the problem

Through our cybersecurity monitoring tools and processes, BD recently identified unauthorised access to a limited portion of its information technology (IT) environment. BD terminated the unauthorised access and applied additional security measures. After a thorough investigation, BD confirmed that product service credentials intended for use by BD technical support teams for certain BD products were accessed by an unauthorised actor. Until these product service credentials are updated, there is a risk of unauthorised access that may impact the confidentiality, integrity and/or availability of the relevant products and associated system or data.

To date, BD has not been made aware of any unauthorised use of these product service credentials and has received no reports of these credentials being used for unauthorised access to any BD device.

Clinical risk

Unauthorised access to BD instruments/systems could be used to disable instruments, corrupt or expose instrument/system databases or modify diagnostic test results. An instrument disablement can delay appropriate diagnosis and treatment. Data corruption or results tampering (where results may either be falsely positive or falsely negative) could cause incorrect diagnosis and inappropriate or absent treatment.

To date, there have been no complaints/adverse events worldwide related to this event.

There is no requirement for customers to return any products as listed in Table 1 to BD. These products can continue to be used in accordance with the guidance in this notice.

IT, Safety and Security Actions to be Taken:

BD encourages customers to follow best practices for maintaining strong security measures to protect hospital networks and medical devices including:

- Ensure access to potentially vulnerable devices is limited to authorised personnel.
- Inform authorised users of issue, and ensure all relevant passwords are tightly controlled.
- Monitor and log network traffic attempting to reach medical device management environments for suspicious activity.
- Where possible, isolate affected devices in a secure VLAN or behind firewalls with restricted access that only permits communication with trusted hosts in other networks when needed.
- Impacted devices do not require use of RDP ports and these should be disabled or blocked if Enabled.
- Ensure permissions on file shares are appropriately established and enforced, and monitor and log access for evidence of suspicious activity.
- Disconnect devices from the network if connectivity is not necessary.

BD Actions:

BD has implemented additional security measures to further strengthen its IT environment.

Actions to be taken by BD:

BD Regional Support teams will be working to contact affected customers to discuss the next steps to be taken, which may include updating credentials and/or software.

Customer Actions:

- Review the products listed in **Table 1** to determine if the products in your possession are

impacted.

- Complete and return the Customer Response Form **even if you no longer use/have the impacted product as listed in Table 1 in your facility by 11th December 2024**.
- Circulate this notification to all those who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

- Identify the facilities where you have distributed affected product and notify them immediately of this notification.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **11th December 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

	End User with Inventory	**End User with ZERO inventory**	**Where to send completed form**
Purchased **directly** from BD	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	BD_EMEA_Notification@bd.com
Purchased from a **distributor/3rd party**	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3rd party

Contact reference person

If you have any questions or require assistance relating to this Field Safety Notice, please contact your local BD representative or the local BD office or email: feedbackinformation_EMEA@bd.com

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to *Advancing the world of health*™. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

Customer Response Form - IDS-25-5176
Product Cybersecurity Matter
REF: See Table 1

Return to BD_EMEA_Notification@bd.com as soon as possible or **no later than the 11th December 2024**.

By signing below, you confirm this Field Safety notice has been read, understood and that all recommended actions have been implemented as required.

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Name of your supplier for this product *(if not direct from BD)**	
Signature:	**Date:**

This form must be returned to BD before this action can be considered closed for your account.

**If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*

Please confirm **ONE** of the following options:

☐ I have one or more affected product(s) within my organisation.

Please provide a contact name of a representative from your organisation who will be the point of contact to organise product remediation, if different from above:

Name:	*Telephone No:*	*Email:*

OR

☐ I confirm that our facility **does not have any** of the affected product listed in this Field Safety Notice.

All product that is not available for remediation will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.