25th July 2024

URGENT: FIELD SAFETY NOTICE – IDS-24-5081

BD Phoenix™ M50 & BD Phoenix™ 100 Instruments

REF: see Table 1 **Serial Numbers:** All serial numbers
Type of Action: Field Work

Attention: Laboratory Managers, Risk Managers, Biomedical Personnel

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

Dear Customer,

BD is issuing a Field Safety Corrective Action for all serial numbers of **BD Phoenix™ M50 instruments and BD Phoenix™ 100 instruments**. According to our distribution records your organisation may have received the impacted product in Table 1.

Manufacturer's SRN: US-MF-000018910

Product Name	Product Code (REF)	Serial Number	UDI
BD Phoenix™ M50 instrument	443624	All serial numbers*	00382904436247
	44362409		00382904436247
BD Phoenix™ 100 Instrument	448100	All serial numbers	00382904481001
	44810009		00382904481001

Table 1: Impacted product

*All serial numbers are impacted that have prior Phoenix M50 System Software Version 2.85.0.0 and PUD V7.41A

This notice is limited to the product codes listed in Table 1. Appendix 1 shows how to identify the instrument software version.

Description of the problem

BD identified through post-market surveillance an increase in the number of complaints for *Escherichia coli* (E. coli) misidentification for clinical samples that were tested on BD Phoenix™ M50 instrument and BD Phoenix™ 100.

This issue impacts customers who are using the system for identification.

Clinical risk

There is a possibility of misidentification of *Escherichia coli* (as another gram-negative organism) with clinical samples tested in the Phoenix System. These erroneous results may lead to misdiagnosis and inappropriate treatment of infections caused by *E. coli*, and potential clinical outcomes, such as the

worsening of underlying infection or extended course and exposure to antibiotics, may be moderate to severe in nature.

To date there has been no adverse events worldwide related to this issue.

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

Clinical User Actions

1. Continue use of the instrument. However, confirmatory testing should be performed on any suspected E. coli misidentifications until BD is able to perform the remediation to correct the issue.

2. It is not necessary to review previous test results and no additional clinical actions are recommended.

BD Actions:

1. BD has identified the root cause and will implement appropriate corrective actions to prevent recurrence of this issue.

2. **For BD Phoenix™ M50 users**: BD will contact your facility to schedule a service visit to provide an update to the PUD (Phoenix Update Data) and software to correct this issue.

3. **For BD Phoenix™ 100 users**: A BD representative will contact your facility regarding next steps.

Customer Actions:

- Immediately inspect your facility to identify if you have the affected product.
    - Refer to Appendix 1 to confirm software version
- Complete and return the Customer Response Form **even if you no longer have any of the impacted product remaining in your facility by 30th August 2024**.
- Circulate this notice 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:

- Immediately inspect your facility to identify if you have the affected product in your inventory.
    - Refer to Appendix 1 to confirm software version
- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **30th August 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	<<insert contact email address here>>
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 e-mail <<insert contact email address here>>.

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-24-5081
BD Phoenix™ M50 & BD Phoenix™ 100 Instruments

Return to **<< insert email address>>** as soon as possible or **no later than the 30th August 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:**

Please confirm the following options:

My facility has the following product (check **ALL** applicable boxes):

☐ **BD Phoenix™ M50 Instrument/s**

☐ **BD Phoenix™ 100 Instrument/s**

OR

☐ I confirm that our facility **does not have any** of the affected instruments.

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

Please provide a contact name of a representative from your organisation who will be the point of contact for BD, if different from above:

Name:	Tel No.:	E-mail:

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.*

Appendix 1 – Software Version Identification

BD Phoenix™ 100	BD Phoenix™ M50
The instrument software & PUD versions for the BD Phoenix™ 100 are in the top/center of the main status screen (Figure 1)	The instrument software & PUD versions for the BD Phoenix™ M50 instrument are in the top/right corner of the Status Tab (Figure 2).
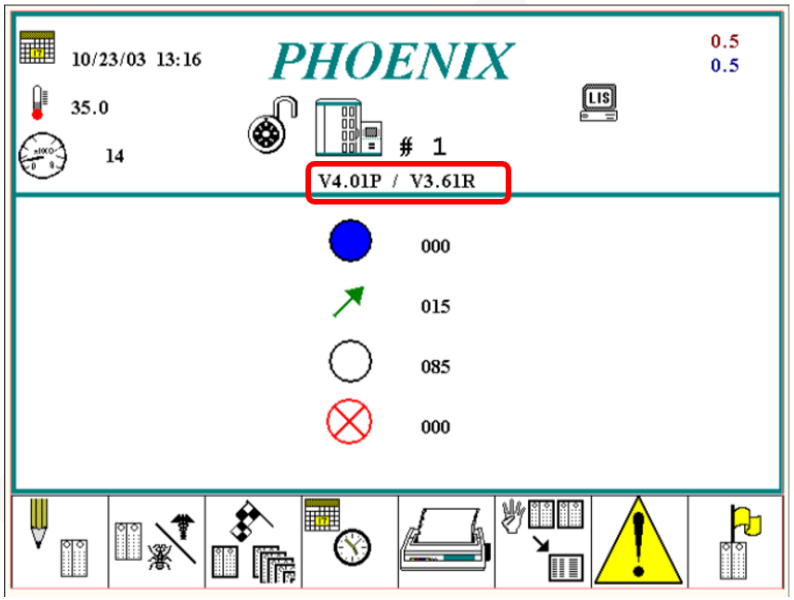	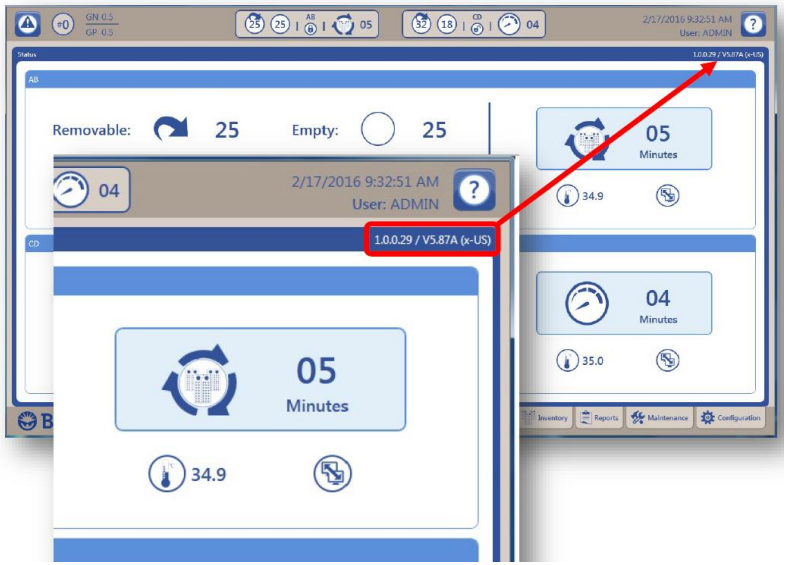
Figure 1	**Figure 2**