



**NOT FOR PUBLICATION -  
FOR NCA REVIEW ONLY**

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www.BD.com

xxxxx 2022

**URGENT: FIELD SAFETY NOTICE – IDS-21-4213 Updated**

**BD Veritor™ Plus Analyzer**

**REF: 256066 Serial Numbers: Unexpired Analyzers up to 31/08/2024**

**Type of Action: Product Removal**

**Attention: Clinical Personnel, Risk Managers, Biomedical Personnel**

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

Dear Customer,

In January 2022, BD issued an advisory Field Safety Notice for all unexpired BD Veritor™ Plus Analyzers reinforcing that **only** the AC power adapter supplied with the device should be used to power the instrument, as stated in the Instructions for Use (IFU) (document number 8091498, revision 09).

Since the distribution of that Field Safety Notice, BD has received further complaints (making a total of 6 complaints) reporting the potential to cause fire. BD's initial investigation indicated that the issue occurred simultaneous with the use of an unauthorized alternative AC/DC power adapter, and not the approved power adapter provided by BD with the BD Veritor™ Plus Analyzer. However, the most recent complaint occurred whilst using the BD Veritor™ Plus Analyzer with the BD provided AC/DC power adapter.

After further review, BD has determined that this action is now being updated from an “advisory” to a “product removal” of unexpired analyzers within an expiry date up to and including August 2024, as shown in Table 1. Due to material supply chain shortages, there will be delays in offering replacement BD Veritor™ Plus Analyzers, therefore if you choose to continue use of the BD Veritor™ Plus Analyzer whilst waiting for your new device, BD recommends following the guidance in Appendix 1 to reduce as much as possible, the risks associated with the described defect.

<b>Product Description</b>	<b>Product Code (REF)</b>	<b>Expiration Date (Up to and including)</b>
BD Veritor™ Plus Analyzer	256066	31/08/2024

**Table 1: Impacted Product**

Impacted devices in Table 1 (above) were shipped by BD beginning 10<sup>th</sup> January 2020.



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**Note:** Analyzers with expiry dates beyond 31<sup>st</sup> August 2024 are not within the scope of this product removal.

### **Clinical Risk**

The risk associated with the defect has not increased since the previous Field Safety Notice. A fire resultant from power issues could cause the user 2nd or 3rd degree burns and/or smoke inhalation should the user have been close enough to the device. Additionally, fire could result in property damage. BD has not received reports of serious injury related to this issue to date.

### **Actions already taken by BD**

Corrective actions have been implemented to mitigate risk of fire from over-voltage for all analyzers currently manufactured and distributed by BD. Analyzers with expiry dates beyond August 2024, were manufactured with overvoltage protection to reduce the risk of overheating when an incorrect power adapter is connected to the device. These devices are not within the scope of this product removal.

### **Actions to be taken by BD**

BD will be replacing BD Veritor™ Plus Analyzers with an expiry date within scope of this Field Safety Notice. Whilst waiting for your new device, BD recommends following the guidance in Appendix 1 to reduce as much as possible, the risks associated with the described defect. If you would prefer not to continue to use your Analyzer, you can dispose of your device following the disposal instructions within the IFU and BD will either replace the device (once available) or credit your account.

BD will provide free of charge labels to customers who have affected BD Veritor™ Plus Analyzers. These labels are to be attached to the BD-supplied AC/DC power adapter(s) in accordance with the instructions in Appendix 1. Please provide appropriate personnel contact details in the Customer Response Form on page 4, so that shipping of these labels can be arranged.

### **Actions for Customers to take**

1. Circulate this Field Safety Notice, including Appendix 1 to all those within your organisation that may use the BD Veritor™ Plus Analyzers.
2. If you have further distributed the product, please identify those users, and notify them at once of this Field Safety Notice, including Appendix 1.
3. Complete the Customer Response Form on page 4 and return it to **<<insert contact details here>>** as soon as possible or no later than xx July 2022.

**Note:** If you no longer use/have the BD Veritor™ Plus Analyzer, it is still important that you return the Customer Response Form for our reconciliation purposes.

4. If you experience any issues with the BD Veritor™ Plus Analyzer report as a complaint as per your normal process.



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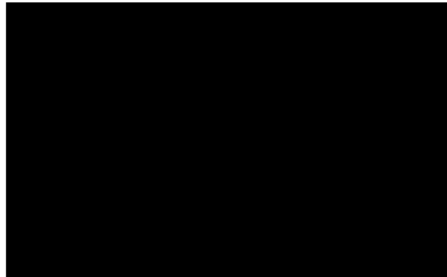
**Contact Reference Person**

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> 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,



Sr. Manager, Post Market Quality  
EMEA Quality

DRAFT



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**Customer Response Form - IDS-21-4213 Updated**

**BD Veritor™ Plus Analyzer**

REF: 256066 Serial Numbers: Unexpired Analyzers up to 31/08/2024

Return the completed & signed form as soon as possible or no later than the xx July 2022 to <<insert fax/email address here>>.

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

**Please check (✓) one of the following three options:**

**Option 1:** I do have BD Veritor™ Plus Analyzers in scope of this Field Safety Notice, and will **continue to use** the device in accordance with the IFU and Appendix 1 until replacements are available

Number of Analyzers: .....

**Option 2:** I do have BD Veritor™ Plus Analyzers in scope of this Field Safety Notice, and will **dispose** of the devices in accordance with the disposal instructions in the IFU

Number of Analyzers: .....

*For Option 2 only please select one:* - I own the device(s) and require; credit , or replacement

- My devices are loaned

*For Option 1 and 2:* Please provide contact information below of a representative from your organisation who BD can contact to arrange shipping of adapter labels / replacement Analyzers or credit.

Contact Name	Job Title	Telephone	Email

**OR**

**Option 3:** I do not have/no longer use the BD Veritor™ Plus Analyser's in scope of this Field Safety Notice

**Account/Organisation Name:**

**Department (if applicable):**

**Address:**

<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	<b>Job Title:</b>
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Signature:</b>	<b>Date:</b>

*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 – BD recommendations for continued Use of BD Veritor™ Plus Analyzer.

### New recommendations provided in **BLUE**

#### 1. When **charging** the BD Veritor™ Plus Analyzer:

- **USE ONLY** the 5V 3A, 15W AC/DC power adapter provided with the BD Veritor™ Plus Analyzers as per the current Instructions for Use (8091498 Revision 09), which can be found at: <https://www.bd.qarad.eifu.online/>
- **MONITOR** the analyzer/s when connected to the power adapter and do not leave unattended.
- **DISCONNECT** the power adapter from the outlet when the analyzer/s are not charging.

If needed, a replacement AC/DC power adapter (catalog number 445201) can be purchased by calling BD Customer Service.

#### 2. When **operating** the BD Veritor™ Plus Analyzer:

- **USE BATTERY POWER** and connect only to the AC/DC power adapter to charge the battery upon depletion.

**Note:** using battery power will disable “walk-away” mode, and the device will turn off automatically after fifteen (15) minutes when not in use.

Using the device under battery power will limit the time the analyzer is connected to the AC/DC power adapter. When using battery power, monitor battery life indicator and plug in to AC/DC power adapter to recharge as required.

#### 3. Consider placing the analyzer on a fire-resistant surface, if possible.

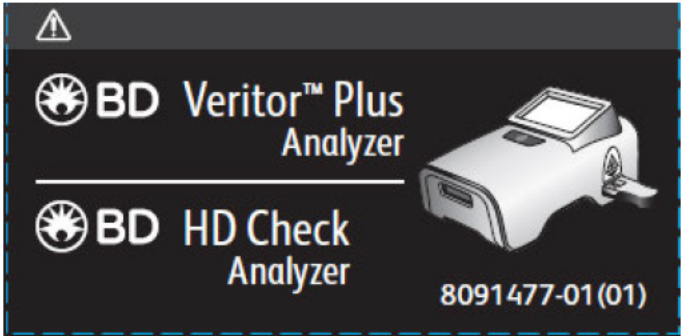
- #### 4. Affix the label(s), which will be provided by BD, to your BD-supplied AC/DC power adapter(s) to ensure the correct power adapter is always connected to the analyzer(s). If you require additional labels, please indicate the request on the Customer Response Form.

**NOTE:** Label should be placed near the barrel connector (end that is connected to the analyzer) for optimal visibility – see picture below for reference;



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