13th January 2022

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear valued Customer,

BD is issuing an advisory Field Safety Notice for all unexpired BD Veritor™ Plus Analyzers (please refer to Table 1 below) and according to our distribution records your organisation may have received the impacted product.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Product Code (REF)</th>
<th>Serial number</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Veritor™ Plus Analyzer</td>
<td>256066</td>
<td>All unexpired analyzers</td>
<td>Between 31/12/2021 and 31/08/2024</td>
</tr>
</tbody>
</table>

Table 1: Impacted Product

Description of the Problem

Based on customer feedback, BD has received 2 complaints reporting that the BD Veritor™ Plus Analyzer may have the potential to overheat and/or cause fire. The issue can occur when an unauthorised AC power adapter, not the one provided by BD with the BD Veritor™ Plus Analyzer, is used to power the instrument.

As a result of this feedback and to mitigate this occurrence, BD is reinforcing that only the AC power adapter supplied with the device should be used to power the instrument, as stated in the IFU (document number 8091498 revision 08). Refer to section 1.5.3 “Summary of Cautions and Warnings” as shown in figure 1 below.
The IFU can also be accessed and downloaded from the following link, please search under the product code (REF) 256066:

https://www.bd.qarad.eifu.online/

Please refer to Appendix 1 below for an image of the AC power adapter that is provided with the BD Veritor™ Plus Analyzer.

This advisory is limited to the product code listed in Table 1 above and affects all analyzers which have an expiry date between the 31st December 2021 to the 31st August 2024.

**Clinical Risk**

A fire resultant from power issues could cause the user 2nd or 3rd degree burns should the user have been close enough to the device. BD has not received reports of serious injury related to this issue to date.

**Actions Taken by BD:**

For future shipments of the BD Veritor™ Plus Analyzer, an additional label will be placed on the power adapter to help users identify the BD Veritor™ Plus Analyzer power adapter.

For existing BD Veritor™ Plus Analyzer users, BD requires that the actions below are taken.

**Actions for Customers to take:**

1. Circulate this Field Safety Notice 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 advisory.

3. **USE ONLY** the AC power adapter provided with the BD Veritor™ Plus Analyzer. Please refer to Appendix 1 below for an image of the AC power adapter that is provided with the BD Veritor™ Plus Analyzer. For AC power adapter setup and cautions please refer to the BD Veritor™ Plus Analyzer Instructions for Use (document number 8091498 revision 08) Section 2.3.

4. If required, a replacement AC power adapter (product code 445201) can be purchased by calling BD Customer Service.

5. Complete the customer response form on page 4 and return to BDUKFieldAction@bd.com as soon as possible or no later than 28th February 2022. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.
There is no requirement for customers to return any BD Veritor™ Plus Analyzer to BD. These products can continue to be used in accordance with the guidance in this safety notice and provided in the BD Veritor™ Plus Analyzer Instructions for Use.

**Contact Reference Person**

If you have any questions about this, please contact your local BD representative or the local BD office on 0800 917 8776, or email BDUKFieldAction@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,

Lorna Darrock
Sr. Manager, Post Market Quality
EMEA Quality
Customer Response Form - IDS-21-4213
BD Veritor™ Plus Analyzer

REF: 256066  Serial Numbers: All Unexpired Analyzers

Please read in conjunction with Field Safety Notice IDS-21-4213 and return the completed and signed form as soon as possible or no later than the 28th February 2022 to BDUKFieldAction@bd.com.

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

<table>
<thead>
<tr>
<th>Account/Organisation Name:</th>
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<tbody>
<tr>
<td>Department (if applicable):</td>
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<td>Address:</td>
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<td>Postcode:</td>
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<td>Contact Name:</td>
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<td>Contact Telephone Number:</td>
<td>Contact E-mail Address:</td>
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<tr>
<td>Signature:</td>
<td>Date:</td>
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</table>

This form must be returned to BD before this action can be considered closed for your account.
Appendix 1 - An image of the AC power adapter supplied with the BD Veritor™ Plus Analyzer.

USE ONLY the following AC power adapter:

Refer to the BD Veritor™ Plus Analyzer Instructions for Use (document number 8091498 Revision 08) Section 2.3 for AC power adapter setup and cautions.