



MEDICAL DEVICE PRODUCT ADVISORY
BD Veritor™ Plus Analyzer

January 5, 2022

Product Name	Catalog No.	UDI	Serial No.	Expiration Date
BD Veritor™ Plus Analyzer	256066	00382902560661	All unexpired analyzers	12/2021 – 08/2024

For the Attention of: Testing Manager

BD is conducting a voluntary product advisory for the BD Veritor™ Plus Analyzer units outlined in the table above.

Description of the problem and health hazard(s):

BD has received two (2) complaints reporting that the BD Veritor™ Plus Analyzer may have the potential to overheat and/or cause fire. BD’s investigation has found that the issue can occur when an unauthorized alternative AC power adapter, and not the one provided by BD with the BD Veritor™ Plus Analyzer, is used to power the instrument.

BD is conducting this action to reinforce that only the AC power adapter supplied with the device should be used to power the instrument. 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 or deaths related to this issue.

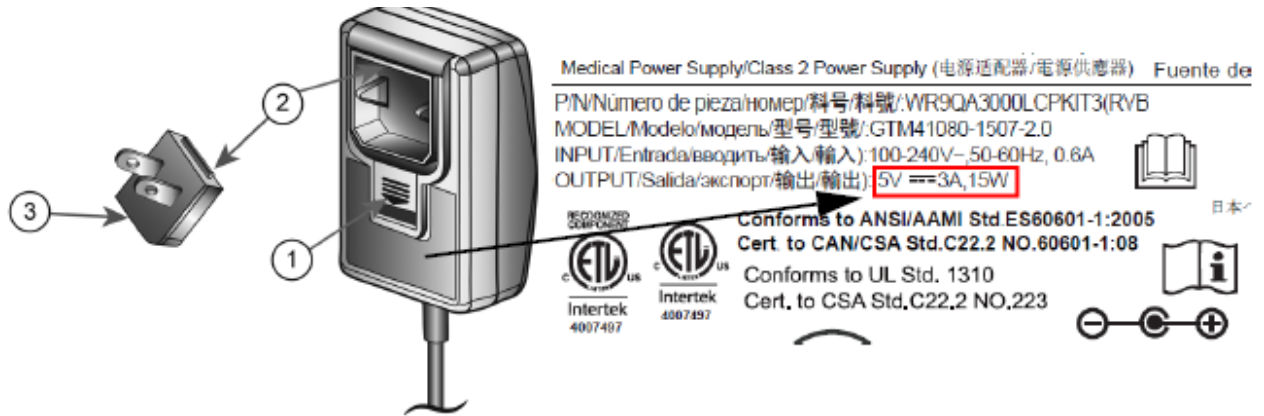
Our records indicate you may have been shipped one or more of the affected instruments beginning on September 24, 2019.

PLEASE TAKE THE FOLLOWING ACTIONS:

1. Ensure the contents of this Product Advisory are read and understood by those within your organization.
2. **USE ONLY** the AC power adapter provided with the BD Veritor™ Plus Analyzers.

An image of the AC power adapter provided with the BD Veritor™ Plus Analyzer is provided below. Refer to the BD Veritor™ Plus Analyzer Instructions for Use (8091498 Revision 08) Section 2.3 for AC power adapter setup and cautions.

USE ONLY the following AC power adapter:



CAUTION

THE ANALYZER WILL NOT CHARGE IF THE POWER ADAPTER OUTPUT IS GREATER THAN 5V 3A, 15W. IF THE BATTERY ICON IS FLASHING OR THE BATTERY CHARGE IS REQUIRED, MAKE SURE THE ANALYZER IS CONNECTED TO THE BD SUPPLIED POWER ADAPTER.

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

3. Share and post this Product Advisory letter within your facility network and forward to any customers you may have distributed the product to ensure awareness.
4. Complete the attached Customer Response Form and return to the BD contact noted on the form so that BD may acknowledge your receipt of this notification.

Actions Taken by BD:

Corrective actions have been initiated to address the identified root cause.

If you require further assistance, please contact:

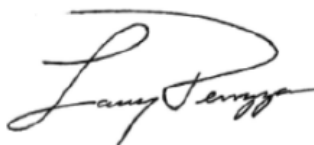
BD Contact	US Contact Information	Areas of Support
North American Regional Complaint Center	Phone: 1-844-8BD-LIFE (1-844-823-5433) Say "Recall" when prompted Mon–Fri 8:00am and 5:00pm CT or Email: productcomplaints@bd.com	Recall questions, Product Complaints, Technical Questions

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,



Nick Petropoulos
VP, Life Sciences
BD-Canada



Larry Perruzza
Sr. Director, Post Market Quality

CUSTOMER RESPONSE FORM

IDS-21-4213-FA

BD Veritor™ Plus Analyzer

Please assist BD by promptly returning this form to BD:

BD Post Market Quality @

Email: BDRC15@bd.com or Fax: (312)-949-0369

Facility: _____
Please print full, current facility name. Do not use initials.

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Customer Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check below:

I have read and understood the attached notice and taken appropriate actions.

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Person/function responsible for the receipt and management of product advisory and recalls at your facility:

Name: _____

Phone: _____

Email: _____

Fax #: _____