



URGENT PRODUCT RECALL

May 31,2017

Customer Name

Product Name	Cat. Number	Serial Numbers
BD Phoenix™ AP Instrument	448010	AP0447, AP0448, AP0449, AP0450, AP0451, AP0458, AP0463

Dear BD Phoenix AP Customer,

BD has recently confirmed a manufacturing issue with the motor that drives movement of the robot arm. The issue may result in the inability of this motor to withstand the lateral forces encountered during normal operations. Should this occur, the instrument will indicate an E20 error-Pipettor step loss during operation and stop functioning. While there is no loss of patient sample, the samples would need to be manually processed until the instrument can be repaired.

Our records indicate the above-referenced product was installed between November 2016 and April 2017.

To limit any disruption in your workload, BD Service will contact you to schedule replacement of your instrument. You may continue to use the instrument until replacement is performed. Please share this recall notification with all users of the product to ensure they are also aware of this recall.

Please complete the attached Customer Response Form so that BD may acknowledge your receipt of this notification. Complete and fax the form to:

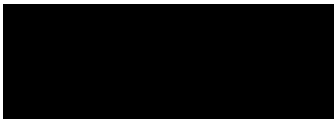
Attention: Regulatory Compliance,

Fax: 410-316-4258 or email to BDRC2@bd.com.

If you require further assistance, please contact BD (Customer/Technical) Support at 1-800-638-8663 in the United States.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with the highest quality products. Thank you for your prompt support on this important matter. BD appreciates your cooperation.

Regards,



Gail Griffiths
Sr Director, Regulatory Compliance

Please assist BD by promptly returning this form to:
BD Regulatory Compliance
Fax #: 410-316-4258
Email: BDRC2@bd.com

Customer Response Form

Phoenix AP

Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ State: _____ Zip: _____

Contact Person: _____

Telephone No.: _____ Email Address: _____

Fax No.: _____

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

Product Name	Catalog No.	Serial Number(s)
BD Phoenix™ AP	448010	Customer serial number

FOR BDDS USE ONLY		
BILL TO ACC'T NO. 9000000446	ORDER REASON 517	DELIVERY P.O. NO.
SHIP TO ACC'T NO.	JUSTIFICATION CODE	INVOICE P.O. NO.