

24 Jul 2019

**FIELD SAFETY NOTICE**

**SPECTRA OPTIA® APHERESIS SYSTEM**  
**System Alarm Discontinues Procedure**

**Product Name: Spectra Optia Apheresis System (Spectra Optia)**  
**Catalog Number: 61000**  
**No affected unit was sold in Singapore.\***

Dear Valued Customer:

Terumo BCT has become aware of an increased prevalence of the “Return pump did not stop” alarm occurring in a portion of the Spectra Optia Apheresis System population. Spectra Optia systems with the serial numbers listed above could exhibit this alarm improperly, resulting in a discontinuation of the procedure.

Terumo BCT is issuing this field safety notice to inform users of the Spectra Optia system about this deficiency and to assure that all potentially affected devices are corrected. You are being notified of this defect because our records indicate that you have received one or more of the identified devices.

This notice advises Spectra Optia operators to observe and respond to all system alarms and their resulting on-screen instructions by following good clinical practice:

- Presentation of the “Return pump did not stop” alarm imparts no immediate risk to the patient or donor connected to the device.
- This system alarm ends the current procedure without the ability to continue the procedure or conduct automated rinseback for an extracorporeal blood volume loss based upon the disposable set type.
- Additional patient/donor procedures could be required based on the timing of the alarm presentation, either immediately following an interrupted procedure or when arrangements can be made to continue therapy.

**ACTIONS BEING TAKEN BY TERUMO BCT**

- a) Terumo BCT is taking action by notifying you of this potential defect in a Spectra Optia system you have from the list of serial numbers above.

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- b) Terumo BCT has identified the cause of this alarm behavior as an artifact of the Pump Driver Circuit Card Assembly and will arrange for inspection of all Spectra Optia systems with this identified defect.
- c) A member of Terumo BCT's technical service team will contact you to arrange for inspection of any potentially affected devices at your facility. Devices containing this defect will be corrected by replacing the Pump Driver Circuit Card Assembly.

### **ACTIONS REQUIRED BY HEALTHCARE PROVIDERS AND DISTRIBUTORS**

1. Distribute this notification to all Spectra Optia system users within your organization.
2. Continue to use your Spectra Optia system(s) in accordance with the operator's manual and the operator training materials.
3. **IMPORTANT:** Complete the attached acknowledgement and fax or email the acknowledgement to Terumo BCT by August 30, 2019. Your return of the acknowledgement is critical so that we can confirm that you have received the field safety notice.

### **CONTACT INFORMATION**

Terumo BCT is dedicated to providing you with the highest quality support and communicating information regarding our products. If you have any questions, please contact your Terumo BCT representative or your regional Customer Support Center at the following contacts:

- Phone: +65 6715 3778
- Fax: +65 6774 1419
- Email: APACSafetyAlert@terumobct.com

Sincerely,



Kelvin Koh  
Director, Regulatory Affairs

*\*Please note that there may be other affected serial numbers globally. Should the Spectra Optia be purchased from an overseas dealer, please verify the serial number with Terumo BCT representative.*

**FIELD SAFETY NOTICE ACKNOWLEDGEMENT**

**Spectra Optia Apheresis System: System Alarm Discontinues Procedure**

**Acknowledgement and Receipt Form**

**Response Is Required**

I have read and understood the instructions provided in the letter of 24 Jul 2019. (Please check one box)

Yes  No

I have additional questions. I would like a Terumo BCT representative to contact me. (Please check one box)

Yes  No

Are there any adverse events (serious injury or death) associated with system alarm discontinues procedure on Spectra Optia that have not been previously reported? (Please check one box)

Yes  No

If yes, please explain:

Affected Serial No(s):

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Facility Name:

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Facility Address:

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**Acknowledger's Details**

Print Name:

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Signature:

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Title:

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Date:

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Telephone:

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Email:

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**Please fax this completed form to +65 6774 1419  
or email it to [APACSafetyAlert@terumobct.com](mailto:APACSafetyAlert@terumobct.com).**