

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.

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.0590
Fax: +32.2.721.0770

Terumo BCT Asia Pte. Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Tokyo Opera City Tower 49F,
3-20-2, Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-1450,
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

- 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

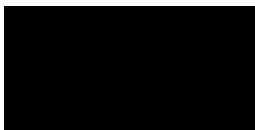
- 1. Distribute this notification to all Spectra Optia system users within your organization.
- 2. Continue to use your Spectra Optia system(s) in accordance with the operator's manual and the operator training materials.
- 3. **IMPORTANT:** Complete the attached acknowledgement and fax or email the 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).: _____

Facility Name: _____

Facility Address: _____

Acknowledger's Details

Print Name: _____

Signature: _____

Title: _____

Date: _____

Telephone: _____

Email: _____

**Please fax this completed form to +65 6774 1419
or email it to APACSafetyAlert@terumobct.com.**