

04 Jun 2019

FIELD SAFETY NOTICE

SPECTRA OPTIA® APHERESIS SYSTEM
Potential for Electronic Connection Intermittency

Product name: Spectra Optia Apheresis System (Spectra Optia)
Catalog: 61000

Affected serial no(s). in Singapore: [REDACTED]

Dear Valued Customer:

Terumo BCT has become aware of an unintended height deviation of the physical supports for a circuit card assembly (CCA) installed in the Spectra Optia equipment. Spectra Optia contained in the serial numbers listed above could exhibit an intermittent electronic connection due to this deviation.

Terumo BCT has **not** received any customer reports of intermittent electronic connections that were identified to have been caused by this identified defect. Terumo BCT is issuing this field safety notice to inform users of the Spectra Optia about this defect and to assure them that all potentially affected devices will be corrected. You are being notified of this defect because our records indicate that you may have received one or more of the identified devices.

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

- No unsafe system behavior has been linked to this deviation.
- All alarms contain on-screen instructions; please follow them accordingly.
- If the system presents repeated alarms across multiple procedures that do not result from a known cause, it may be necessary to end the procedure.

ACTIONS BEING TAKEN BY TERUMO BCT

- a) Terumo BCT is taking action by notifying you of this potential defect in a Spectra Optia because our records indicate that you may have received one or more of the identified devices.
- b) In addition to this letter, Terumo BCT will arrange for inspection of all Spectra Optia with the CCA card assembly supports that potentially contain this identified defect. A member of Terumo BCT's technical service team will contact you to arrange for inspection of any potentially affected devices at your facility. Any identified devices containing this defect

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will be corrected by replacing the housing that contains the CCA card assembly supports. Devices that are not affected will not require correction.

ACTIONS REQUIRED BY HEALTHCARE PROVIDERS AND DISTRIBUTORS

1. Distribute this notification to all Spectra Optia users within your organization.
2. Continue to use your Spectra Optia in accordance with the operator's manual and the operator training materials.
3. If any Spectra Optia present repeated alarms across multiple procedures that do not result from a known cause, it may be necessary to end the procedure.

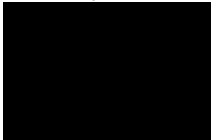
IMPORTANT: Complete the acknowledgement and fax or email the acknowledgement to Terumo BCT by **5th Jul 2019**. Your return of the acknowledgement is critical so that we can confirm that you have received the field safety notice.

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 numbers:

- Phone: +65 6715 3778
- Fax: +65 6774 1419

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.*