November 2026

FSN Ref: FA73 – Spectra Optia AIM Management FSCA Ref: FA73 – Spectra Optia AIM Management

Field Safety Notice

Voluntary Medical Device Safety Alert Notification

For Attention of*:Spectra Optia users utilising version 12.1.0

Contact details of local representative (name, e-mail, telephone, address etc.)*
Terumo BCT Europe NV, Ikaroslaan 41B-1930, Zaventem, Belgium

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Field Safety Notice (FSN)

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Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Spectra Optia™ Apheresis System
1.	2. Commercial name(s)
	Spectra Optia™ Apheresis System
1.	3. Unique Device Identifier(s) (UDI-DI)
	5020583OptiaSysGW
1.	4. Primary clinical purpose of device(s)*
	The Spectra Optia Apheresis System consists of dedicated equipment, software, disposable sets, and accessories that are used for the extracorporeal separation and processing of blood components. The separated blood components may be collected for reinfusion or transfusion or exchanged with donor cell or replacement solutions.
1.	5. Device Model/Catalogue/part number(s)*
	This notification applies to Red Blood Cell Exchange (RBCX), RBC Depletion (RBCD), RBC Depletion/Exchange (RBCD/X), Therapeutic Plasma Exchange (TPE), and TPE With a Secondary Plasma Device (TPE With SPD) procedures performed on Spectra Optia devices using software version 12.1.
1.	6. Software version
	Version 12.1.0
1.	7. Affected serial or lot number range
	All serial numbers for version 12.1.0
1.	8. Associated devices
	N/A

Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Terumo Blood and Cell Technologies has identified a condition relating to the inability to disable AIMS in patients with dark plasma following alarms. This issue is specific to Spectra Optia software version 12.1.0 while performing the procedures referenced in section 1.5 above.
2.	2. Hazard giving rise to the FSCA*
	In patients with dark plasma associated with underlying disease states such as sickle cell disease or liver disease, operators may experience recurring Automated Interface Management (AIM) system-related alarms that cannot be cleared. Specifically, these are the “AIM system saw red blood cells near top of connector” alarm 4509 for all RBCX procedures and alarm 5512 for TPE and SPD procedures.
2.	3. Probability of problem arising
	35 complaints in relation to the customer being unable to proceed due to these alarms and not being able to clear the alarm condition have been received within the past three (3) years. These runs had the alarms ‘cells at top of the connector’ or ‘cells detected in plasma line from centrifuge’ and mentioned the AIM disable button was not available. This issue has the potential to occur on all devices that use software v12.1.0 and running an

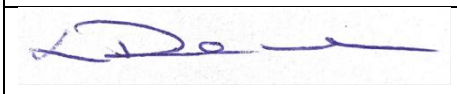
	exchange procedure. To date, only one (1) of the 35 occurrences has led to the requirement for additional medical intervention.
2.	4. Predicted risk to patient/users
	The general patient population being treated with plasma exchange is unlikely to experience issues with the AIMS system. The population at greatest risk can experience a delay in treatment if the AIMS systems cannot be disabled after multiple alarms. The option of performing a manual exchange for a failed RBCX is at the physician's discretion. There is no manual equivalent for plasma exchanges.
2.	5. Further information to help characterise the problem
	Patient physiology may lead to continuous alarms which cannot be cleared on Spectra Optia version 12.1.0
2.	6. Background on Issue
	N/A
2.	7. Other information relevant to FSCA
	If an alarm occurs, the healthcare professional should evaluate the possible causes and follow the alarm-screen troubleshooting instructions. Operators are expected to review those possible causes and follow the displayed actions, including evaluating hematocrit entries, inlet-line restrictions, optical components, air bubbles, and other possible causes identified on the alarm screen. If the alarm persists because of patient physiology and cannot be cleared on a system operating software version 12.1, the healthcare professional should assess whether continued treatment is safe and determine the appropriate clinical course based on the patient's condition and the procedure being performed.

	3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other: Continue to follow all alarm-screen instructions and troubleshooting guidance provided by the Spectra Optia system. Spectra Optia systems operating software version 12.1.0 may continue to be used while these instructions are followed. ☐ None	
3.	2. By when should the action be completed?	Complete the attached acknowledgement and fax or email the acknowledgement to EMEAProduct.FSN@terumobct.com by January 31, 2027. Your return of the acknowledgement is critical so we can confirm that you have received the information.
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

<table>
<tr><td>3.</td><td colspan="2">5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

1. Terumo Blood and Cell Technologies is notifying customers operating Spectra Optia software version 12.1.0 of this issue.
2. The AIM disable button functionality is available on all released software versions other than 12.1.0.
3. Terumo Blood and Cell Technologies can provide additional guidance, as applicable, regarding software management.</td></tr>
<tr><td>3.</td><td>6. By when should the action be completed?</td><td>Complete the attached acknowledgement and fax or email the acknowledgement to EMEAProduct.FSN@terumobct.com Technologies by January 31, 2027. Your return of the acknowledgement is critical so we can confirm that you have received the Safety Alert.</td></tr>
<tr><td>3.</td><td colspan="2">7. Is the FSN required to be communicated to the patient /lay user? No</td></tr>
<tr><td rowspan="2">3.</td><td colspan="2">8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</td></tr>
<tr><td colspan="2">N/A</td></tr>
</table>

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Terumo BCT, Inc.
	b. Address	10811 W. Collins Ave. Lakewood CO 80215 USA
	c. Website address	www.terumobct.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	1. FSN Customer Reply Form
4.	10. Name/Signature	**Laura Devine** **Vigilance Compliance Sr Specialist**
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.