

April 2025

Spectra Optia[™] Apheresis System Software Version 12.1 Update – Disabling the Automated Interface Management (AIM) System

Dear Valued Customer,

Terumo Blood and Cell Technologies is dedicated to providing you with the highest quality support and remains committed to communicating information regarding our products. This letter is to inform you of a change made in Spectra Optia software version 12.1 to the availability of the Disable AIM button on some alarm screens generated by the Automated Interface Management (AIM) system.

In software version 12.1, the **Disable AIM** button was removed from the "AIM system saw red blood cells near top of connector" alarm screen for the Therapeutic Plasma Exchange (TPE), Red Blood Cell Exchange (RBCX), and Secondary Plasma Exchange (SPD) protocols. The "AIM system saw red blood cells near top of connector" alarm is generated when the system detects the interface is too high in the collect connector and can be generated for several known reasons, including actual shifts in fluid balance, incorrect data entry, and individual patient blood physiology. The decision to remove the option to disable the AIM system from this alarm screen was made to prevent accidental deactivation of the AIM system. This is critical for patient and donor safety, because once the AIM system is disabled, it cannot be re-enabled during the current procedure. Operators should follow the instructions on the alarm screen to troubleshoot the possible causes of the alarm and make procedural adjustments as necessary.

However, we do recognize that there may be scenarios in which the AIM system may need to be disabled to deliver effective therapy. As such, in the next software release, we have opted to reinstate the **Disable AIM** button on the alarm screen on the fourth occurrence of the alarm condition. This software is expected to be available in most countries as early as Summer 2025. With the upcoming release of software version 12.1.1, we encourage customers who have not yet upgraded to version 12.1 to transition directly to version 12.1.1 upon its release.

We appreciate your continued support and look forward to serving you. If you have any questions, please contact your local Terumo Blood and Cell Technologies representative or visit TerumoBCT.com/Contact-Us to obtain more information.

Sincerely,

Keith M. Kazmer

Product Manager, Global Therapy Innovations

Kuth M Kaymun

Spectra Optia™ is either a registered trademark or trademark of Terumo BCT, Inc. in the United States and/or other countries. See TerumoBCT.com/Trademarks for details.

10811 West Collins Ave. Lakewood, Colorado 80215-4440

USA Phone: 1.877.339.4228 Phone: +1.303.231.4357

Fax: +1.303.542.5215

Europe, Middle East and Africa Ikaroslaan 41 1930 Zaventem Belaium

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 C1428DZF **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-Shiniuku. Shinjuku-ku, Tokyo 163-1450, Japan

Phone: +81.3.6743.7890 Fax: +81.3.6743.9800