

April 2024

Spectra Optia™ Apheresis System, Software Version 12.1 – North America

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 Terumo Blood and Cell Technologies products. The purpose of this letter is to inform you of the latest enhancements in Spectra Optia software version 12.1.

The changes made in software version 12.1 do not affect the intended use, performance, patient safety profile, or efficacy of the Spectra Optia system. Terumo Blood and Cell Technologies has verified the Spectra Optia software version 12.1 in accordance with our design control requirements. Any validation required by your facility should be conducted according to your change control process.

Software version 12.1 will be available in the summer of 2024 for your Spectra Optia system. The new software is designed to fortify cybersecurity measures and improve usability of the system.

Discontinuation of support for prior versions of software will take place within 18 months of software version 12.1 becoming available. You will be notified of availability during the summer of 2024. Please work with your Terumo Blood and Cell Technologies representative to arrange for this mandatory upgrade. The upgrade will happen during your preventative maintenance service call during the 18-month period following software availability.

Usability Improvements

- **Alarm mitigation:** Spectra Optia system software has been modified to mitigate the occurrence of "Safety system detected software communication error" alarms and subsequent reboot of the system (sometimes referred to as "watchdog reboots"). Additional measures were implemented to mitigate "Inlet line prime failed" alarm occurrences.
- **Automatically pause pumps when converting to single-needle procedures:** The system will automatically pause the pumps when converting to single-needle in therapeutic plasma exchange (TPE) and red blood cell exchange (RBCX) procedures.
- **Max run time for TPE and TPE-SPD procedures:** The maximum run time allowed for TPE procedures and therapeutic plasma exchange with a secondary plasma device (TPE With SPD) procedures has been changed from 480 minutes to 360 minutes to reflect the validated maximum run time associated with the Spectra Optia™ Exchange Set. The system alerts the operator if the run target extends the procedure beyond 360 minutes.
- **Splash screen:** The splash screen displayed during system boot-up has been modified to show the Terumo logo. The software version and sub-version (Spectra Optia V12.1) are also displayed.
- **UDI symbol definition:** The unique device identifier (UDI) symbol used on the System tab on the Configuration screen is defined in the *Spectra Optia Apheresis System Operator's Manual Addendum, Software Version 12 (2023)*.

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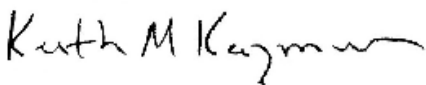
Cybersecurity Measures

- **Cybersecurity:** The device's operating system has been updated, and a firewall has been implemented to strengthen cybersecurity when the device is connected to a network. Additional cybersecurity risk reduction guidelines for denial of service (DOS) attacks have been added to the *Spectra Optia Apheresis System Operator's Manual Addendum, Software Version 12 (2023)*.
- **Summary report messages:** Additional event messages are included in the procedure's summary report.
- **Loss of network alarm:** A new alarm screen has been added to alert the operator in the event the network connection is lost.
- **MAC address:** To assist in network configuration, the MAC address of the device is displayed on the "Config," "Network," "Device Network" screen. Information on MAC address has been added to the *Spectra Optia Apheresis System Operator's Manual Addendum, Software Version 12 (2023)*.
- **Expanded connectivity options:** When sharing device logs through the Cadence™ Data Collection System, network administrators now have more port options to choose from. Information on port configuration has been added to the *Spectra Optia Apheresis System Operator's Manual Addendum, Software Version 12 (2023)*.
- **Real-time messaging connectivity:** If a connection to the server cannot be established while using real-time messaging, the software will now close transport layer security (TLS) sockets to prevent the user interface from freezing.
- **Instructions for device networking:** Instruction has been added to the *Spectra Optia Apheresis System Administration and Data Export Guide (2023)* on how to set up a secure file transfer protocol (SFTP) server as well as instructions for connecting your device to the Cadence Data Collection System or a network time protocol (NTP) server.
- **Data export clarification:** The descriptions of XML fields in the *Spectra Optia Apheresis System Data Management Supplement (2023)* have been rewritten to align more accurately with the current XML fields exported by the device in the procedure's summary report via real-time messaging.

A detailed summary of procedural enhancements, with sample screenshots, is included in the *Spectra Optia Apheresis System Version 12.1 Software Updates Training Presentation* that accompanies this letter. Every Spectra Optia operator should review the content of this presentation prior to performing a procedure with version 12.1 software.

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](https://www.terumobct.com/contact-us) to obtain more information.

Sincerely,



Keith M. Kazmer
Product Manager, Therapeutic Apheresis and Cell Collections