

April 2019

Now Available: Spectra Optia® Apheresis System Software Enhancements, Updated Operator's Manual and Single-Needle Red Blood Cell Exchange (SN-RBCX) Protocol in the U.S.

Dear Valued Customer,

Terumo BCT is dedicated to providing you with the highest quality support and remains committed to communicating information regarding Terumo BCT products. This letter is to inform you about the exciting release of the latest Spectra Optia system enhancements in software version 12.0. Additionally, the Spectra Optia operator's manual is being revised to include an important custom-prime alert.

Software Version 12.0

Software version 12.0 is an optional upgrade that can be installed on your Spectra Optia system during a future Terumo BCT field service visit. The version 12.0 software is designed to provide additional capability to the Red Blood Cell Exchange (RBCX) protocol (including SN-RBCX and expanded hematocrit limits for the depletion/exchange procedure), enhanced data connectivity features (including electronic data export that is compatible with StafaCT cell therapy software) and an improved overall experience of the Spectra Optia system.

A detailed summary of enhancements with sample screenshots is included in the Spectra Optia Version 12.0 Software Updates Training Document (part number TS-OPTI-00008) included with this letter. Every Spectra Optia system operator should read this document prior to performing a procedure with the version 12.0 software.

The version 12.0 software is intended to enhance usability. Any revalidation required by your facility should be conducted according to your internal operating procedures.

Single-Needle (SN) Option for the RBCX Protocol

Increasing the versatility of the Spectra Optia system in the U.S., a single-needle option has been added to the RBCX protocol. SN-RBCX provides Spectra Optia users the added flexibility to address their vascular access needs, a critical component for all apheresis procedures.

Spectra Optia system software version 12.0, the version 12.0 supplement kit (part number 705249-000) and a single-needle adapter (catalog number 11220) are required for SN-RBCX procedures. The updated Spectra Optia operator's manual kit (part number 705072-002) is also required for customers upgrading to version 12.0. Customers purchasing new Spectra Optia devices will receive the updated Spectra Optia operator's manual in the Spectra Optia language kit (part number 705244-004). Please contact your local Terumo BCT representative for details.

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Updated Spectra Optia Operator's Manual

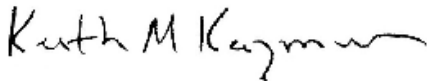
With the release of version 12.0 software, be aware of the custom prime feature when using single-needle mode in patients with low blood volume. To remind users, the following warning was added:

“To avoid potential side effects and complications for patients that have a low blood volume (LBV) or a low hematocrit (Hct), the Spectra Optia Apheresis System recommends performing a custom prime of the tubing set for patients whose extracorporeal volume (ECV) is greater than 10% or 15% of their total blood volume (TBV), or if their extracorporeal red blood cell volume (ERCV) is greater than 10% or 15% of their red blood cell volume (RCV). The attending physician should prescribe the appropriate procedural settings for the patient.”

These details are included in the updated Spectra Optia operator's manual (part number 777379-199).

We appreciate your continued support and look forward to serving you. If you have any questions, please contact your local Terumo BCT representative or the global Customer Support Center, 1.877.3.FYI BCT (394 228) or 303.231.HELP (4357).

Sincerely,



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