Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K132429 - 1217 pages
COMPANY:	TERUMO BCT, INC.. (TERUBCT)
PRODUCT:	SEPARATOR, AUTOMATED, BLOOD CELL AND PLASMA, THERAPEUTIC (LKN)
SUMMARY:	Product: SPECTRA OPTIA APHERESIS SYSTEM, SPECTRA OPTIA SYSTEM SOFTWARE, SPECTRA
DATE REQUESTED:	Oct 13, 2015
DATE PRINTED:	Oct 13, 2015

Note: Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

DEC - 6 2013

510(k) Summary

Owner/Manufacturer:	Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	Tina O'Brien Senior Regulatory Affairs Specialist Phone: (303) 239-2082
Date of Summary Preparation:	August 2, 2013
Trade Name:	Spectra Optia® Apheresis System
Common Name:	Apheresis System
Classification Name:	Automated Blood Cell Separator
Product Code:	LKN
Predicate Device:	Spectra Optia Apheresis System

Device Description: The Spectra Optia Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major sub-systems: (1) the apheresis machine itself (centrifuge, pumps, valves, etc.), (2) sterile, single-use, disposable tubing sets and, (3) embedded software.

Modifications to the disposable Exchange Set and embedded software have been made to enable Red Blood Cell Exchange (RBCx) procedures on the Spectra Optia system.

Intended Use:
The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications, and may be used to perform Red Blood Cell Exchange, Depletion, and Depletion/Exchange (RBCX) procedures.

Indications for Use:
The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Technological Comparison:
The system's base technology is not changed by the introduction of the RBCx protocol.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Discussion of Non-clinical Data:
The modified Spectra Optia system software was verified through a variety of verification testing; including Functional, Reliability, Usability, Exploratory, and Robustness.

Discussion of Clinical Data:
A prospective, multi-center, single-arm, open-label study was conducted to demonstrate that the Spectra Optia's RBCx protocol could consistently achieve the target HbS in the target population as prescribed by the physician. The study resulted in all primary endpoints being met with no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported.

Substantial Equivalence:
Provided below is a summary of substantial equivalence.

Table 1: Spectra Optia system vs. COBE Spectra

	Spectra Optia system (Subject Device)	*COBE Spectra system (K831004)*
Intended Use	Therapeutic Plasma Exchange and **Red Blood Cell Exchange**	Multiple therapeutic apheresis procedures, including **Red Blood Cell Exchange**
Essential Technology	Both the Spectra Optia and COBE Spectra systems are automated blood cell separators achieving their essential function (the separation of blood cells and plasma) through centrifugation.	
Software	Software algorithms underlying the red blood cell exchange procedures on both the Spectra Optia and COBE Spectra systems are controlled by the same equations.	
Performance	In both a "simulated-use" laboratory validation study and human clinical trial, Spectra Optia's RBCx protocol was found to perform the same as the COBE Spectra RBCx protocol, with respect to the system's ability to achieve patient hematocrit targets and to maintain patient fluid balance.	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Terumo BCT, Inc.
Tina O' Brien
Sr. Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215

Re: K132429
Trade/Device Name: Spectra Optia® Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: November 1, 2013
Received: November 4, 2013

Dear Tina O' Brien,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

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medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

Indications for Use

510(k) Number (if known): K132429

Device Name: **Spectra Optia® Apheresis System**

Indications for Use:

The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.12.09 20:01:36 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Terumo BCT, Inc.
Tina O' Brien
Sr. Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215

Re: K132429
Trade/Device Name: Spectra Optia® Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: November 1, 2013
Received: November 4, 2013

Dear Tina O' Brien,

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You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

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Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: **K132429/S001 – Terumo BCT, Inc.**

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Gema Gonzalez -S 2013.12.06 15:20:27 -05'00'
Branch Chief Sign-Off *Acting BC for CYN*	David A. Pudwill -S Acting for CYN 2013.12.06 16:58:46 -05'00'
Division Sign-Off	Benjamin R. Fisher -S 2013.12.09 19:59:38 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

cc: DCC – sign-off & original
ODE/DRGUD/RNDB – (Gema Gonzalez)

Final: KAS:kas:clr:12/6/2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

Indications for Use

510(k) Number (if known): K132429

Device Name: **Spectra Optia® Apheresis System**

Indications for Use:

The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.12.09 20:01:36 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

K132429

FDA CDRH DMC

AUG 1 4 2013

Received

August 12, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Attn: Division of Reproductive, Gastro-Renal, and Urological Devices

RE: Traditional 510(k) Submission
Spectra Optia® Apheresis System
Protocol Modification: *Red Blood Cell Exchange (RBCx)*
Replacement eCopy

Dear Sir or Madam:

In accordance with Section 510(k) of the Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807 Subpart E, Terumo BCT respectfully submits this Premarket Notification for a new therapeutic protocol for the Spectra Optia system, Red Blood Cell Exchange (RBCx) referencing the previously cleared 510(k)'s listed in the table below.

510(k) Number	Subject of 510(k)	510(k) Clearance Date
K071079	Spectra Optia Apheresis System - Therapeutic Plasma Exchange	08/02/2007
K831004	IBM 8400 Automated Blood Cell Separator/ COBE Spectra Apheresis System	09/12/1983

ADMINISTRATIVE INFORMATION

This information is also provided in Section 2 and is provided here for reviewers' convenience.

Type of 510(k) Submission:	Traditional
Device Type:	Common Name: Therapeutic Apheresis System Classification Name: Separator, Automated, Blood Cell and Plasma, Therapeutic Trade Name: Spectra Optia® Apheresis System
510(k) Submitter:	Terumo BCT 10811 W. Collins Avenue Lakewood, CO 80215-4415 Establishment Registration Number: 1722028

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5315

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Europe, Middle East and Africa
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Phone: +32.2.715.05.90
Fax: +32.2.771.07.79

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Fax: +852.2576.1311

Terumo BCT Latin America S.A.
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Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Ebisu South One Bldg. 9F
1-7-8, Ebisu-minami,
Shibuya-ku, Tokyo 150-0022
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contact:	Tina O'Brien Senior Regulatory Affairs Specialist (303) 239-2082 / (303) 231-4756 (FAX)
Confidentiality Preference:	Should be treated as confidential as set forth and defined in 21 CFR 807.95
Recommended Classification Regulation:	21 CFR 864.9245
Class:	Unclassified
Panel:	Gastroenterology/Urology
Product Code:	LKN

BASIS FOR THE SUBMISSION

Terumo BCT respectfully submits the enclosed 510(k) notification for a new therapeutic protocol for the Spectra Optia system, Red Blood Cell Exchange (RBCx). The content of this notification is limited to detailed software, disposable, and labeling information because the protocol will be implemented via an upgrade to the system's software and modified disposable tubing set only. The content of this submission demonstrates substantial equivalence of the Spectra Optia Apheresis System's RBCx protocol to that available on the COBE Spectra Apheresis System (K831004).

This notification is supported by pre-clinical bench testing and a clinical study conducted under IDE #G120048. The clinical trial was resultant of a 5/13/2011 Pre-IDE Meeting (No. I090388), which occurred due to a deficiency letter for our original RBCx 510(k) submission (K093887), which has since been withdrawn. Due to the Agency's requirement for clinical data to support a pre-market notification for RBCx, we conducted a single-arm, multisite study to evaluate the Spectra Optia's ability to achieve targeted (individually prescribed) Hemoglobin S (HbS) levels in adults and children with sickle cell disease (SCD). The results of this study are presented in Section 20.

DESIGN AND USE OF THE DEVICE

Question	Yes	No
Is the device intended for prescription use?	X	
Is the device intended for over the counter?		X
Does the device contain components derived from a tissue or other biologic source		X
Is the device (disposable tubing set) provided sterile?	X	
Is the device (disposable tubing set) intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.543.6015

Terumo BCT Europe N.V.
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Terumo BCT (Asia Pacific) Ltd.
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311 Gloucester Road
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Fax: +852.2576.1311

Terumo BCT Latin America S.A.
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C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
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1-7-8, Ebisu-minami,
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Please note that some documents included in this submission pre-date Terumo BCT and may contain headers with previous company names of CaridianBCT or Gambro BCT. Additionally, the Spectra Optia system may be referenced within some documentation under its research and development name Therapeutic Apheresis Operating System or "TAOS."

Terumo BCT is providing an eCopy of this submission, which is an exact duplicate of the paper copy.

If you should have any questions regarding the technical content of this submission, please do not hesitate to contact Tina O'Brien via telephone at (303) 239-2082, facsimile (303) 231-4756 or email at tina.obrien@terumobct.com. If you should have any questions regarding the electronic format of this submission, please contact Shawna Smith via telephone at (303) 239-2256, facsimile (303) 231-4756 or email at shawna.smith@terumobct.com.

Yours sincerely,

Tina O'Brien

Tina O'Brien
Senior Regulatory Affairs Specialist
(303) 239-2082 / (303) 231-4756 (FAX)
tina.obrien@terumobct.com

Submission: 1 Replacement eCopy

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K132429

FDA CDRH DMC
AUG 05 2013
Received

August 2, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Attn: Division of Reproductive, Gastro-Renal, and Urological Devices

RE: Traditional 510(k) Submission
Spectra Optia® Apheresis System
Protocol Modification: *Red Blood Cell Exchange (RBCx)*

Dear Sir or Madam:

In accordance with Section 510(k) of the Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807 Subpart E, Terumo BCT respectfully submits this Premarket Notification for a new therapeutic protocol for the Spectra Optia system, Red Blood Cell Exchange (RBCx) referencing the previously cleared 510(k)'s listed in the table below.

510(k) Number	Subject of 510(k)	510(k) Clearance Date
K071079	Spectra Optia Apheresis System - Therapeutic Plasma Exchange	08/02/2007
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Device Type:	Common Name: Therapeutic Apheresis System Classification Name: Separator, Automated, Blood Cell and Plasma, Therapeutic Trade Name: Spectra Optia® Apheresis System
510(k) Submitter:	Terumo BCT 10811 W. Collins Avenue Lakewood, CO 80215-4415 Establishment Registration Number: 1722028
Contact:	Tina O'Brien Senior Regulatory Affairs Specialist (303) 239-2082 / (303) 231-4756 (FAX)

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Confidentiality Preference:	Should be treated as confidential as set forth and defined in 21 CFR 807.95
Recommended Classification Regulation:	21 CFR 864.9245
Class:	Unclassified
Panel:	Gastroenterology/Urology
Product Code:	LKN

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Yours sincerely,

Tina O'Brien

Tina O'Brien
Senior Regulatory Affairs Specialist
(303) 239-2082 / (303) 231-4756 (FAX)
tina.obrien@terumobct.com

Submission: 1 Original, 2 eCopies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 Medical Device User Fee Cover Sheet

As required, please find Form FDA 3601: Medical Device User Fee Cover Sheet on the following page. The payment identification number for this traditional 510(k) is (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

TERUMOBCT INC
10810 W COLLINS AVENUE
LAKEWOOD
CO 80215
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****5788

2. CONTACT NAME
Tina OBrien

2.1 E-MAIL ADDRESS
tina.obrien@terumobct.com

2.2 TELEPHONE NUMBER (include Area code)
303-2392082

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted] 17-Jul-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

2 CDRH Premarket Review Cover Sheet (Form FDA #3514) and Certification of Compliance with ClinicalTrials.gov Requirements (Form FDA #3674)

Please find completed Forms FDA 3514 and 3674 attached.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Section 2 - 2
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08-02-2013	(b)(4) [redacted] 3	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☒ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Terumo BCT, Inc.	Establishment Registration Number *(if known)*: 1722028		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 303-239-2082		
Street Address: 10811 W. Collins Ave	FAX Number *(including area code)*: (303) 231-4756		
City: Lakewood	State / Province: CO	ZIP/Postal Code: 80215	Country: US
Contact Name: Tina O'Brien			
Contact Title: Sr. Regulatory Affairs Specialist	Contact E-mail Address: tina.obrien@terumobct.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
PSD Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify):*

Addition of protocol for the conduct of red blood cell exchange procedures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LKN	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K831004	1	IBM 8400 Automated Blood Cell Separator / COBE Spectra Apheresis System	1	Terumo BCT, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Separator, automated, blood cell and plasma, therapeutic

	Trade or Proprietary or Model Name for This Device		Model Number
1	Spectra Optia Apheresis System	1	61000
2	Spectra Optia system software	2	Version 9.0
3	Spectra Optia Exchange Disposable Set	3	10220
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K093887	2 I090388	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code

LKN

C.F.R. Section *(if applicable)*

Classification Panel

Gastroenterology/Urology

Device Class

- [ ] Class I
- [ ] Class II
- [ ] Class III
- [x] Unclassified

Indications *(from labeling)*

The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the medical management of Sickle Cell Disease in adults and children.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839, Released by CDRH on 12-8-2015

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Terumo BCT, Inc.		Establishment Registration Number 1722028		
Division Name *(if applicable)*		Phone Number *(including area code)* 303-232-6800		
Street Address 10811 W. Collins Ave		FAX Number *(including area code)* 303-231-4756		
City Lakewood		State / Province CO	ZIP Code 80215	Country US
Contact Name Dave Hanlon	Contact Title Vice President, Quality		Contact E-mail Address david.hanlon@terumobct.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-0839, Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   Terumo BCT, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   08-02-2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   10811 W. Collins Avenue
   Lakewood, CO 80215

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 303-239-2082
   (Fax) 303-231-4756

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Spectra Optia Machine (Catalog number 61000)

   Spectra Optia Exchange Disposable Set (Catalog #10220)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

   ☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

   ☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

    NCT Number(s): NCT01736657

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
    Tina O'Brien
    Digitally signed by Tina O'Brien
    DN: cn=Tina O'Brien, o=Terumo BCT, ou=Regulatory Affairs, email=tina.obrien@terumobct.com, c=US
    Date: 2013.08.02 10:36:12 -06'00'
    Sign

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Tina O'Brien
    (Title) Senior Regulatory Affairs Specialist

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    10811 W. Collins Avenue
    Lakewood, CO 80215

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 303-239-2082
    (Fax) 303-231-4756

15. DATE OF CERTIFICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

PSC Publishing Services (301) 443-6740 EF

Records processed under FOIA Request #2014-9889, Released by CDRH on 12-8-2015

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date -** This is the date of the application/submission which the certification accompanies.

3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.

9. **Certification -** This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11 -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14. -** Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

August 2, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Attn: Division of Reproductive, Gastro-Renal, and Urological Devices

RE: Traditional 510(k) Submission
Spectra Optia® Apheresis System
Protocol Modification: *Red Blood Cell Exchange (RBCx)*

Dear Sir or Madam:

In accordance with Section 510(k) of the Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807 Subpart E, Terumo BCT respectfully submits this Premarket Notification for a new therapeutic protocol for the Spectra Optia system, Red Blood Cell Exchange (RBCx) referencing the previously cleared 510(k)'s listed in the table below.

510(k) Number	Subject of 510(k)	510(k) Clearance Date
K071079	Spectra Optia Apheresis System - Therapeutic Plasma Exchange	08/02/2007
K831004	IBM 8400 Automated Blood Cell Separator/ COBE Spectra Apheresis System	09/12/1983

ADMINISTRATIVE INFORMATION

This information is also provided in Section 2 and is provided here for reviewers' convenience.

Type of 510(k) Submission:	Traditional
Device Type:	Common Name: Therapeutic Apheresis System Classification Name: Separator, Automated, Blood Cell and Plasma, Therapeutic Trade Name: Spectra Optia® Apheresis System
510(k) Submitter:	Terumo BCT 10811 W. Collins Avenue Lakewood, CO 80215-4415 Establishment Registration Number: 1722028
Contact:	Tina O'Brien Senior Regulatory Affairs Specialist (303) 239-2082 / (303) 231-4756 (FAX)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Confidentiality Preference:	Should be treated as confidential as set forth and defined in 21 CFR 807.95
Recommended Classification Regulation:	21 CFR 864.9245
Class:	Unclassified
Panel:	Gastroenterology/Urology
Product Code:	LKN

BASIS FOR THE SUBMISSION

Terumo BCT respectfully submits the enclosed 510(k) notification for a new therapeutic protocol for the Spectra Optia system, Red Blood Cell Exchange (RBCx). The content of this notification is limited to detailed software, disposable, and labeling information because the protocol will be implemented via an upgrade to the system's software and modified disposable tubing set only. The content of this submission demonstrates substantial equivalence of the Spectra Optia Apheresis System's RBCx protocol to that available on the COBE Spectra Apheresis System (K831004).

This notification is supported by pre-clinical bench testing and a clinical study conducted under IDE #G120048. The clinical trial was resultant of a 5/13/2011 Pre-IDE Meeting (No. I090388), which occurred due to a deficiency letter for our original RBCx 510(k) submission (K093887), which has since been withdrawn. Due to the Agency's requirement for clinical data to support a pre-market notification for RBCx, we conducted a single-arm, multisite study to evaluate the Spectra Optia's ability to achieve targeted (individually prescribed) Hemoglobin S (HbS) levels in adults and children with sickle cell disease (SCD). The results of this study are presented in Section 20.

DESIGN AND USE OF THE DEVICE

Question	Yes	No
Is the device intended for prescription use?	X	
Is the device intended for over the counter?		X
Does the device contain components derived from a tissue or other biologic source		X
Is the device (disposable tubing set) provided sterile?	X	
Is the device (disposable tubing set) intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

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Please note that some documents included in this submission pre-date Terumo BCT and may contain headers with previous company names of CaridianBCT or Gambro BCT. Additionally, the Spectra Optia system may be referenced within some documentation under its research and development name Therapeutic Apheresis Operating System or "TAOS."

Terumo BCT is providing an eCopy of this submission, which is an exact duplicate of the paper copy.

If you should have any questions regarding the technical content of this submission, please do not hesitate to contact Tina O'Brien via telephone at (303) 239-2082, facsimile (303) 231-4756 or email at tina.obrien@terumobct.com. If you should have any questions regarding the electronic format of this submission, please contact Shawna Smith via telephone at (303) 239-2256, facsimile (303) 231-4756 or email at shawna.smith@terumobct.com.

Yours sincerely,

Tina O'Brien

Tina O'Brien
Senior Regulatory Affairs Specialist
(303) 239-2082 / (303) 231-4756 (FAX)
tina.obrien@terumobct.com

Submission: 1 Original, 2 eCopies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 3.1

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s
http://www.fda.gov/cdrh/ode/guidance/1567.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	Yes Section 1		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	Yes Section 2		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes Section 3		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	Yes Section 4		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	Yes Section 5		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	Yes Section 6		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html	Yes Section 7		
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators	Yes Section 8		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html. FDA Standards program www.fda.gov/cdrh/stdsprog.html. Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html	Yes Section 9		

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes Section 10		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes Section 11		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	Yes Section 12		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	Yes Section 13		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	Yes Section 14		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	Yes Section 15		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	Yes Section 16		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	Yes Section 17		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes Section 18		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes Section 19		

Title	Related Information	Present	Inadequate	N/A
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf	Yes Section 20		

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Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): _____

Device Name: **Spectra Optia® Apheresis System**

Indications for Use:

The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 510(k) Summary

Terumo BCT requests that the attached Summary for this version of the Spectra Optia system be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this premarket 510(k) notification.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

Owner/Manufacturer:	Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	Tina O'Brien Senior Regulatory Affairs Specialist Phone: (303) 239-2082
Date of Summary Preparation:	August 2, 2013
Trade Name:	Spectra Optia® Apheresis System
Common Name:	Apheresis System
Classification Name:	Automated Blood Cell Separator
Product Code:	LKN
Predicate Device:	Spectra Optia Apheresis System

Device Description: The Spectra Optia Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major sub-systems: (1) the apheresis machine itself (centrifuge, pumps, valves, etc.), (2) sterile, single-use, disposable tubing sets and, (3) embedded software.

Modifications to the disposable Exchange Set and embedded software have been made to enable Red Blood Cell Exchange (RBCx) procedures on the Spectra Optia system.

Intended Use:
The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications. The system may be used to perform the following procedures:
• Therapeutic Plasma exchange (TPE)
• Red Blood Cell exchange, depletion, and depletion/exchange procedures (RBCx)

Technological Comparison:
The system's base technology is not changed by the introduction of the RBCx protocol.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Discussion of Non-clinical Data:
The modified Spectra Optia system software was verified through a variety of verification testing; including Functional, Reliability, Usability, Exploratory, and Robustness.

Discussion of Clinical Data:
A prospective, multi-center, single-arm, open-label study was conducted to demonstrate that the Spectra Optia's RBCx protocol could consistently achieve the target HbS in the target population as prescribed by the physician. The study resulted in all primary endpoints being met with no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported.

Substantial Equivalence:
Provided below is a summary of substantial equivalence.

Table 1: Spectra Optia system vs. COBE Spectra

	Spectra Optia system (Subject Device)	***COBE Spectra system (K831004)***
Intended Use	Therapeutic Plasma Exchange and **Red Blood Cell Exchange**	Multiple therapeutic apheresis procedures, including **Red Blood Cell Exchange**
Essential Technology	Both the Spectra Optia and COBE Spectra systems are automated blood cell separators achieving their essential function (the separation of blood cells and plasma) through centrifugation.	
Software	Software algorithms underlying the red blood cell exchange procedures on both the Spectra Optia and COBE Spectra systems are controlled by the same equations.	
Performance	In both a "simulated-use" laboratory validation study and human clinical trial, Spectra Optia's RBCx protocol was found to perform the same as the COBE Spectra RBCx protocol, with respect to the system's ability to achieve patient hematocrit targets and to maintain patient fluid balance.	

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6 Truthful and Accuracy Statement

I certify that, in my capacity as Vice President of Regulatory Affairs of Terumo BCT, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

10 June, 2013

Mark Holmes
VP, Regulatory Affairs

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7 Class III Summary and Certification

Not applicable, as this device is currently unclassified.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8 Financial Certification

Form FDA #3454 (*Certification: Financial Interests and Arrangements of Clinical Investigators*) is provided in **Attachment 8.1**. The clinical study that supports this notification and its respective principal investigators are listed below. Participating clinical investigators were not employed by Terumo BCT as neither part- nor full-time employees.

Investigational Site:	(b)(4) [redacted]
Kosair Children's Hospital	
University of Colorado at Denver	
Children's of Alabama	
Johns Hopkins Medical	
Children's Hospital Oakland (CHO)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 8.1
Form FDA #3454
Certification: Financial Interests and Arrangements of Clinical Investigators

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b)(4)

[redacted]

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Raymond Goodrich, Ph.D	Vice President, Scientific and Clinical Affairs
FIRM/ORGANIZATION Terumo BCT, Inc.	
SIGNATURE	DATE *(mm/dd/yyyy)* 7/5/2013

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Declarations of Conformity & Summary Reports

Terumo BCT does not claim conformance in whole or in part to the any standards for the purposes of this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10. Executive Summary

Terumo BCT has developed a new therapeutic protocol for the Spectra Optia system, Red Blood Cell Exchange (RBCx). This additional protocol represents an enhancement to the platform's overall clinical utility and represents a new intended use for the device.

A comprehensive history of 510(K) clearances for the Spectra Optia system through CDRH is provided in **Table 1**.

Table 1: Spectra Optia 510(k) Clearance History (CDRH)

System Component	CDRH* 510(k) Clearance(s)
Spectra Optia Equipment	K071079 – original Spectra Optia submission K103090 – addition of Return Air Line Detector (RLAD) K113480 – software version 6.1 BK130031 - modified standard filler
Spectra Optia Software	K071079 – original Spectra Optia submission K103090 – addition of Return Air Line Detector (RLAD) K113480 – software version 6.1
Spectra Optia Exchange Set	K071079 – original Spectra Optia submission

*Please note that ***software modifications*** reviewed and cleared by CBER are specific to protocols under their purview and do not impact Therapeutic Plasma Exchange (TPE) or Red Blood Cell Exchange (RBCx), thus, these CBER clearance numbers are not provided.

10.1 Regulatory History and Submission Purpose

FDA originally cleared the Spectra Optia system (equipment, disposable Exchange Set, and software) for the intended use of Therapeutic Plasma Exchange (see K071079) in August 2007. In August 2008, Pre-IDE Meeting No.I090388 was held to discuss the regulatory pathway for adding the RBCx procedure to the Spectra Optia system's Indications for Use. As agreed upon during that meeting, a 510(k) was submitted (K093887) in which the safety and functionality of the RBCx apheresis procedure was demonstrated by a simulated-use laboratory validation study, while the protocol's therapeutic efficacy was supported by its long history of effective clinical use - as documented in the published literature.

After a 14 month review cycle, the FDA requested additional information to support the RBCx 510(k)'s clearance in a February 2011 letter. The additional information requested included results from a prospective clinical study examining the clinical utility of RBCx

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

on the Spectra Optia system for a specific indication/patient population. Subsequently, the submission (K093887) was withdrawn.

Terumo BCT met again with FDA in May 2011 (Pre-IDE Meeting No. I090388 – meeting minutes provided in **Attachment 10.1**) to discuss the type of clinical evidence that FDA required for clearance of RBCx on the Spectra Optia system. Pursuant to that discussion with the Agency, Terumo BCT conducted a multi-site, single-arm study to evaluate the Spectra Optia system's ability to achieve targeted (individually prescribed) Hemoglobin S (HbS) levels in adults and children with sickle cell disease (SCD), that included red blood cell exchange, depletion, and depletion/exchange procedures. Terumo BCT presents the findings of this study herein to support 510(k) clearance of the RBCx protocol on the Spectra Optia Apheresis System.

10.2 Device Description

General Description

The Spectra Optia Apheresis System is comprised of three major sub-systems, (1) the machine itself which consists of an automated, centrifugal, blood-cell separation device that uses pumps, valves and sensors to control and monitor the extracorporeal circuit, during therapeutic apheresis procedures, (2) a single-use, disposable tubing set, and (3), the system software.

The machine consists of an automated, centrifugal, blood-cell separation device that uses pumps, valves and sensors to control and monitor the extracorporeal circuit, during therapeutic apheresis procedures. An exterior view of the Spectra Optia machine and disposable tubing set is presented in ***Figure* 1**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 1: Spectra Optia system

Spectra Optia System Software, Version 9.0

The Spectra Optia System's software controls pump flow rates and centrifuge speed to establish and maintain the required RBC/plasma interface. The system's Graphical User Interface (GUI) allows the user to communicate with and control the device. Automated systems ensure patient/donor safety, while allowing operator control.

The RBCx protocol is implemented via an upgrade of the system's software to Version 9.0, which also contains the TPE currently cleared for use in the United States (K071079). Please note that other protocols not currently cleared in the U.S. are also included in Version 9.0, but are disabled on systems sold within the U.S.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Spectra Optia Exchange Disposable Set - Catalog #10220

As detailed in Section 11, minor modifications to the disposable Spectra Optia Exchange Set were made to accommodate RBCx procedures. A schematic of the Exchange Set is shown in ***Figure 2***.

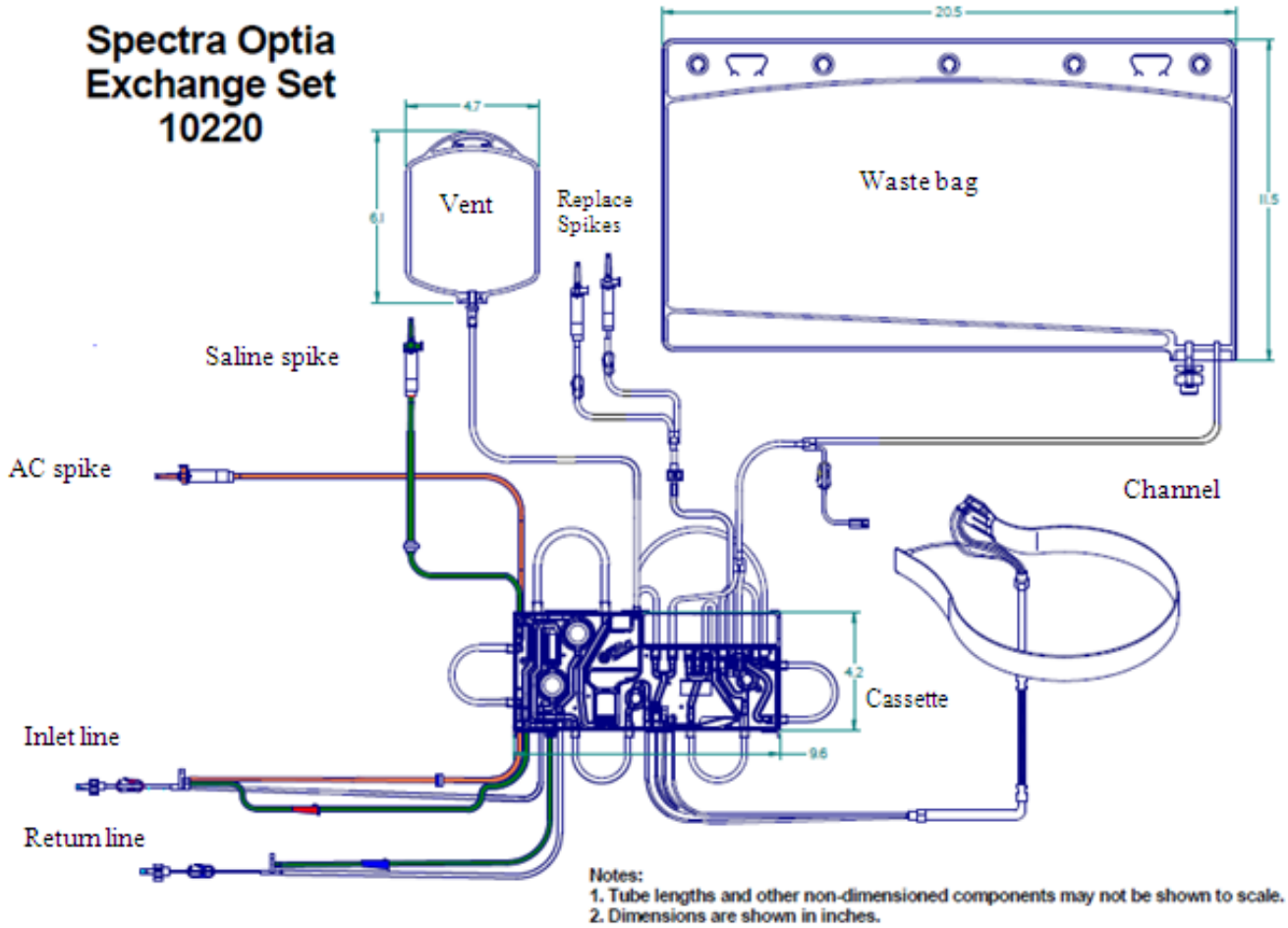

Figure 2: Single-use, Disposable Exchange Set – Catalog #10220

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10.3 Indications for Use

The proposed indication for use statement is provided below:

The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the transfusion management of Sickle Cell Disease in adults and children.

10.4 Device Comparison

As detailed in the tables below, the predicate device for the Spectra Optia system's Red Blood Cell Exchange (RBCx) Protocol is the COBE Spectra Apheresis System.

Table 2: Device Summary

		510(k) No.	**Clearance Date**	**Intended Use**
Subject Device	**Spectra Optia Apheresis System**	TBD	TBD	Therapeutic Plasma Exchange and **Red Blood Cell Exchange**
Predicate Device	**IBM 8400 Automated Blood Cell Separator / COBE Spectra Apheresis System**	K831004	09/12/1983	Multiple therapeutic apheresis procedures, including **Red Blood Cell Exchange**

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Table 3: Device Comparison: Red Blood Cell Exchange Conducted on the Spectra Optia and COBE Spectra Systems

	Spectra Optia system (Subject Device)	**COBE Spectra system (K831004)**
Intended Use	Therapeutic Plasma Exchange and **Red Blood Cell Exchange**	Multiple therapeutic apheresis procedures, including **Red Blood Cell Exchange**
Essential Technology	Both the Spectra Optia and COBE Spectra systems are automated blood cell separators achieving their essential function (the separation of blood cells and plasma) through centrifugation.	
Software	Software algorithms underlying the red blood cell exchange procedures on both the Spectra Optia and COBE Spectra systems are controlled by the same equations.	

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	Spectra Optia system (Subject Device)	**COBE Spectra system (K831004)**
Performance	In both a "simulated-use" laboratory validation study and human clinical trial, Spectra Optia's RBCx protocol was found to perform the same as the COBE Spectra RBCx protocol, with respect to the system's ability to achieve patient hematocrit targets and to maintain patient fluid balance.	

Table 4: Technological Comparison of Spectra Optia and COBE Spectra systems

Attribute	**Spectra Optia Apheresis System (Subject Device)**	**COBE Spectra Apheresis System (Predicate Device)**
RBCx Hematocrit Accuracy	Median difference: 0.565 units 95% CI: 0.3-0.9	Median difference: 1.000 units 95% CI: 0.-3.0
RBCx Hematocrit Accuracy	Median: 0.565 95% CI: 0.3-0.9	Median: 1.000 95% CI: 0.-3.0
RBCx Fluid Balance Accuracy	Median: 1.15 95% CI: 0.4-1.6	Median: 1.4 95% CI: 0.3-3.2
Separation Technology	Continuous flow centrifuge, based on One-Omega, Two-Omega Loop Technology	Continuous flow centrifuge, based on One-Omega, Two-Omega Loop Technology
Channel Technology	Single-stage	Dual-stage and Single-stage
Control Mechanisms		
Interface Management	Automatic	Manual
Mechanical Features		
Drive Train	Gear train	Gear train
Pump/Valve Technology	Peristaltic pumps and rotary valves	Peristaltic pumps and rotary valves
Sensor Technology	Access Pressure Return Pressure Centrifuge Pressure AC Bubble Detector Basin Leak RBC Detector Door Latch Ultrasonic Level Detector	Access Pressure Return Pressure Centrifuge Pressure AC Bubble Detector Basin Leak RBC Detector Door Latch Ultrasonic Level Detector
Filtration	Sterile Barrier Filters on ACDA and Saline Lines Filters in the Inlet and Return Lines	Sterile Barrier Filters on ACDA and Saline Lines Filters in the Inlet and Return Lines
Disposables		
Blood-contacting	Biocompatible, same materials as	Biocompatible, same materials as

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Attribute	**Spectra Optia Apheresis System (Subject Device)**	**COBE Spectra Apheresis System (Predicate Device)**
Materials	used in other previously cleared Terumo BCT disposables	used in other previously cleared Terumo BCT disposables
Software		
User Interface Type	Graphical User Interface	Text-based LED Display
Software & Electronics Architecture	Independent Control and Safety Systems, using two microprocessors	Independent Control and Safety Systems, using eight microprocessors
Electronics		
CPU's	Pentium Class	Microprocessors
Enclosures	E-box – Isolates EMI, etc.	E-box – Isolates EMI, etc.
Communications	Ethernet	Serial

10.5 Pre-Clinical Testing Summary

A laboratory-based, comparative study of the COBE Spectra and Spectra Optia systems was performed to demonstrate the equivalence of Red Blood Cell Exchange procedures conducted on the subject and predicate device platforms.

Study Design: Simulated Patient Conditions: Blood bags representing a panel of six simulated patient conditions were prepared using controlled procedures for laboratory evaluation. The simulated conditions (blood bags) were constructed to represent actual clinical patients that commonly present for each of the three RBCx procedure types (exchange, depletion, and depletion/exchange). Testing using this simulated patient panel was replicated three times on both platforms. Key RBCx procedure outcomes were compared across the apheresis systems using conventional parametric and nonparametric statistical techniques. The laboratory experiment was statistically sized, based on a non-inferiority hypothesis. Additional Spectra Optia RBCx procedures were conducted using 42-day-old stored blood, waste sickle-cell blood and needle (vs. luer lock) connections to the blood bags, to further demonstrate the platform's robustness.

Outcome Measures: The primary outcome measure was the ability of each device to achieve targeted mid-run (depletion/exchange procedures) and end-of-run (all procedures) hematocrits. Hematocrit measurements were used as a surrogate endpoint for the fraction of (defective) cells remaining (FCR). Secondary outcome measures included fluid balance, hemolysis (measured for procedures conducted with waste sickle-cell blood, 42-day-old stored blood, and when using needles at high flow rates), and procedure time.

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Results: With respect to the study's primary outcome measure, the Spectra Optia system achieved target hematocrits more accurately than did COBE Spectra. The (statistically significant) median difference between the targeted and measured hematocrits was .56 hematocrit units for the Spectra Optia system vs. 1 hematocrit unit for the predicate COBE Spectra device. For the study's secondary outcome measures (fluid balance, hemolysis, and procedure time), the two platforms performed essentially the same. No significant hemolysis was detected for Spectra Optia, even when day-old sickle-cell waste products or 42-day-old stored red blood cells (RBCs) were processed. Finally, procedure or "run" times were similar between the two devices.

10.6 Clinical Testing Summary

The Evaluation of the Spectra Optia Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease (ESSENTIAL) study was conducted to validate the Spectra Optia RBCx protocol.

Study Objective: The purpose of this study is to evaluate the performance of the Spectra Optia system red blood cell exchange (RBCx) protocols (exchange and depletion/exchange) in study participants with sickle cell disease.

Design Overview: The ESSENTIAL study was a prospective, multi-center, single-arm, open-label study design. Patients with sickle cell disease meeting the enrollment criteria were consented (or assented, as appropriate) and enrolled in the study until 60 subjects completed the requirements of the Evaluable population. Of the 60 subjects, 40 adults and 20 children were enrolled who were to have an RBC exchange or RBC depletion/exchange procedure either as part of a chronic program or as a single procedure.

The type of treatment procedure (RBC exchange or RBC depletion/exchange) was based on the investigator's recommendation.

Outcome Measures: The primary endpoint will evaluate the mean ratio of the *Actual Fraction of Cells Remaining* (*FCRa*; as measured by Post-Procedure % HbS) to the *Predicted Fraction of Cells Remaining* (*FCRp*; as predicted by the Spectra Optia system FCR algorithm), in the Evaluable subject population.

Results: The ESSENTIAL study successful met its primary endpoint by demonstrating that the ratio of actual to predicted fraction of cells remaining following the RBCx

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procedure (0.92,) was well within the pre-specified boundaries. The 95% CI (0.883, 0.963) demonstrates that the system is functioning as intended and all secondary efficacy endpoints were met. Additionally, there were reports of patients experiencing SAEs, UADEs, or patients who withdrew from the procedure or treatment due to an AE.

Conclusion: The Spectra Optia Apheresis System performs safely and effectively for the conduct of RBCx procedures in adults and children with Sickle Cell Disease.

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Attachment 10.1

(b)(4)

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(b)(4)

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11. Device Description

11.1 Spectra Optia System

The Spectra Optia Apheresis System is comprised of three major sub-systems, (1) the machine itself (**Figure 1**) which consists of an automated, centrifugal, blood-cell separation device that uses pumps, valves and sensors to control and monitor the extracorporeal circuit, during therapeutic apheresis procedures, (2) a disposable tubing set, and (3), the system software. The RBCx protocol will be implemented via an upgrade to the system's software and modification to the disposable tubing set.

Figure 1: Spectra Optia system

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Spectra Optia System Software, Version 9.0

The Spectra Optia software enables the designated procedure, in the case of this submission, the RBCx protocol. The software obtains operator input and controls and monitors the system's hardware. The software is organized across three independent computer subsystems: (referred to as) Control, Safety, and Automated Process Control (APC). The control subsystem software controls pump flow rates, centrifuge speed and valves to establish and maintain the required red blood cell (RBC)/plasma interface. It utilizes algorithms and state machines to execute a procedure (protocol). The safety subsystem software independently monitors the hardware and the control. The APC software controls and monitors the Automated Interface Control (AIM) imaging system, which is used to optimize blood component separation.

The embedded Spectra Optia system software is an accumulation of all available protocols. Upon clearance, the RBCx protocol will be implemented in the U.S. on Version 9.0 software, on which the currently cleared TPE protocol (K071079) will also be enabled.

Spectra Optia Exchange Disposable Set - Catalog #10220

The disposable Spectra Optia Exchange Set (Catalog #10220) is a modification to the disposable Exchange Set that the FDA cleared (K071079) for the conduct of Therapeutic Plasma Exchange (Catalog #10200). Terumo BCT has implemented a minor change to the set to accommodate Red Blood Cell Exchange (RBCx) procedures (used in IDE #G120048). The changes to the Exchange Set will allow operators to use the Spectra Optia system Exchange Set for TPE (both access options) and RBCx procedures. Detailed schematics of the kit are shown in **Figure 2** and provided in **Attachment 11.1**.

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Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

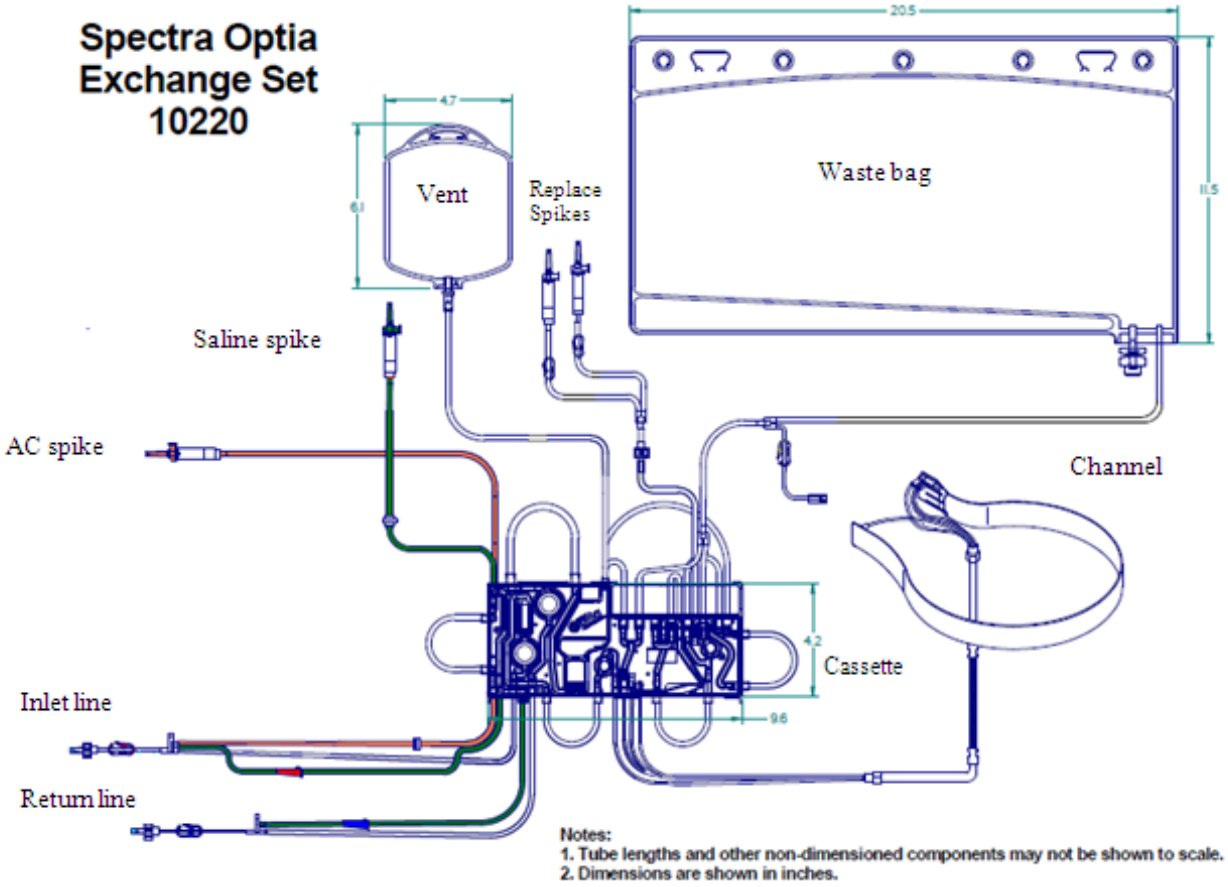

Figure 2: Single-use, Disposable Exchange Set – Catalog #10220

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The cassette of the tubing set is loaded onto the front of the Spectra Optia system (**Figure 3**), while the channel and connector are loaded into the system filler inside the centrifuge chamber (**Figure 4**).

Figure 3: Loading the Cassette

Figure 4: Loading the Channel and Connector

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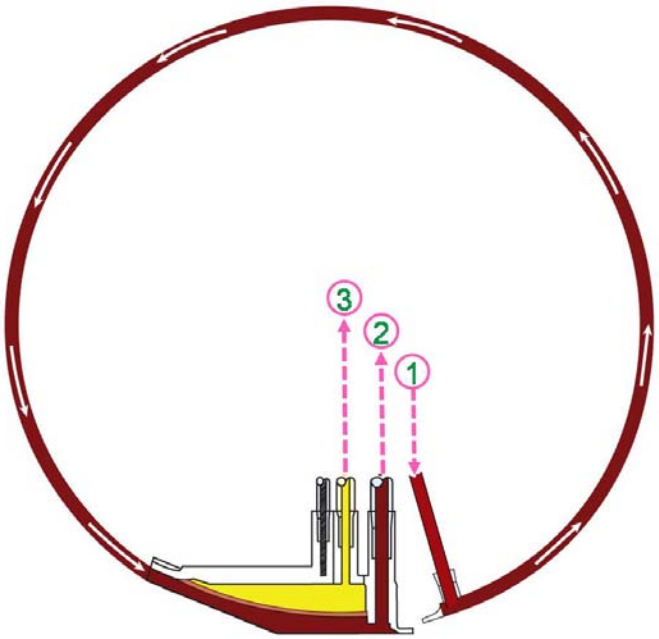
The Channel and Connector are the components of the tubing set that assist with component separation during the procedure (**Figure 5**). The function of the connector is to provide a place for the blood to separate into the plasma, buffy coat, and RBC layers. Separation of the whole blood occurs in the channel. Based on the specific gravity of the cells, centrifugal force separates the plasma, buffy coat, and RBC from the whole blood as it enters the connector.



1. Anticoagulated whole blood enters the channel to separate the RBCs from the buffy coat and plasma.

2. RBCs passively flow to the remove bag.

3. Plasma is pumped to the replacement fluid line where it mixes with the replacement fluid to be pumped to the reservoir.

Figure 5: Channel and Connector Overview

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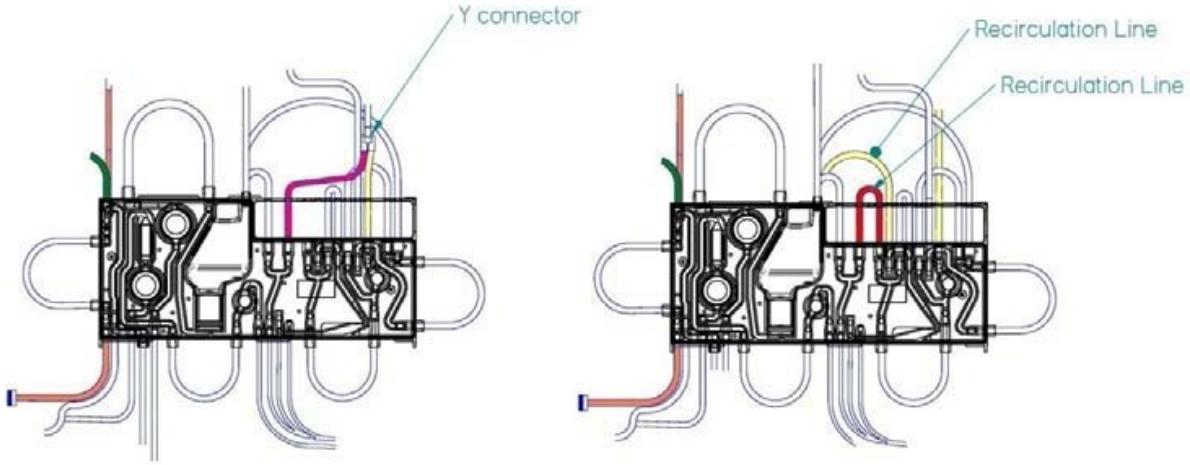
The Spectra Optia Exchange Set, Catalog #10200 (previous) and Spectra Optia Exchange Set Catalog #10220 (current) kits are compared in ***Figure 6***. As shown, only the flow path of the set's tubing and connectors differs between the two catalog numbers. This minor change to the set's flow path supports the RBCx protocol, while the flow path for TPE procedures remains unchanged. This minor change did not require new materials, processes, or changes to the set packaging.

Specifically, the difference between the 10200 kit (TPE only) and the 10220 kit (RBCx and TPE) consists of re-routing the RBC re-circulation line to the waste bag line via a Y connector (noted in ***Figure 6*** in red). This allows either plasma or red cells to be routed to the waste bag. In the case of plasma exchange, the plasma is routed to the waste bag. In the case of red blood cell exchange, red cells are routed to the waste bag. The fluid path is defined by the valve position of the red cell and plasma lines.



TPE & RBCx Kit – Catalog #10220 **TPE Only Kit- Catalog #10200**

Figure 6: Comparison of the 10220 Kit vs. the 10200 Kit

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11.2 Red Blood Cell Exchange (RBCx) Protocol

The Spectra Optia Red Blood Cell Exchange procedure includes three functions: red blood cell exchange, red blood cell depletion, and a combined function - red blood cell depletion/exchange. All of these functions remove red blood cells (RBCs) from patients while providing appropriate replacement fluids. The only difference between an exchange and a depletion procedure is the type of replacement fluid used. During an exchange procedure, the system removes defective RBCs from the patient and replaces them with healthy donor RBCs. During a depletion procedure, the system removes excessive or defective RBCs from the patient and replaces them with a non-cellular replacement fluid (for example, albumin or saline). During the combined depletion/exchange, the system performs a depletion procedure and then transitions to an exchange procedure.

The objectives of the Spectra Optia Apheresis System RBCx procedure are: (1) to remove defective or excessive red blood cells, (2) to infuse healthy replacement RBCs or a non-cellular replacement fluid, (3) to change the patient's hematocrit per the physician's prescription, and, (4) to maintain fluid balance.

The Spectra Optia Red Blood Cell Exchange procedure achieves its therapeutic objectives by separating whole blood into its plasma and cellular components, including red cells, removing the cellular components, and returning the separated plasma to the patient. Fluid balance is maintained by adding replacement fluid to the returned plasma. This apheresis process is described in the following steps:

1) The patient is connected to the contiguous, single-use, disposable Exchange Set via needles or catheters. The tubing set includes two lines, one for venous whole blood access, and a second line for the return of blood components to the patient

2) The incoming whole blood is mixed with anticoagulant (AC), to prevent clotting while the blood is outside the body.

3) The anti-coagulated whole blood is transported via pumps to the centrifuge, where it is continuously separated into plasma and cellular components in the channel of the disposable set. The Exchange Set's channel connector is illustrated below in ***Figure 7***.

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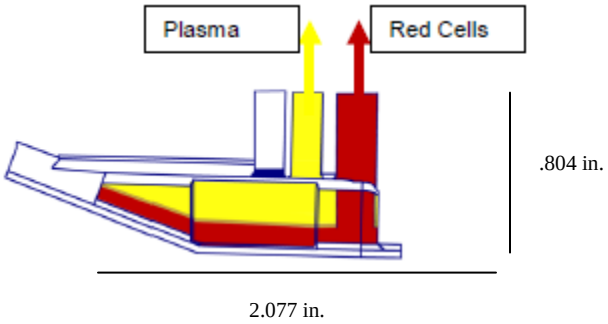

Figure 7: Channel Connector

4) As shown in ***Figure 8***, the plasma component is then pumped from the channel and mixed with replacement RBCs or a non-cellular replacement fluid before being returned to the reservoir. From the reservoir, it is then pumped back to the patient via the return line.

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Figure 8: Cassette Flow Path

5) The cellular component, including red cells, AC and some residual plasma, passively exits the channel and is routed to the set's Remove Bag (see ***Figure 2***).

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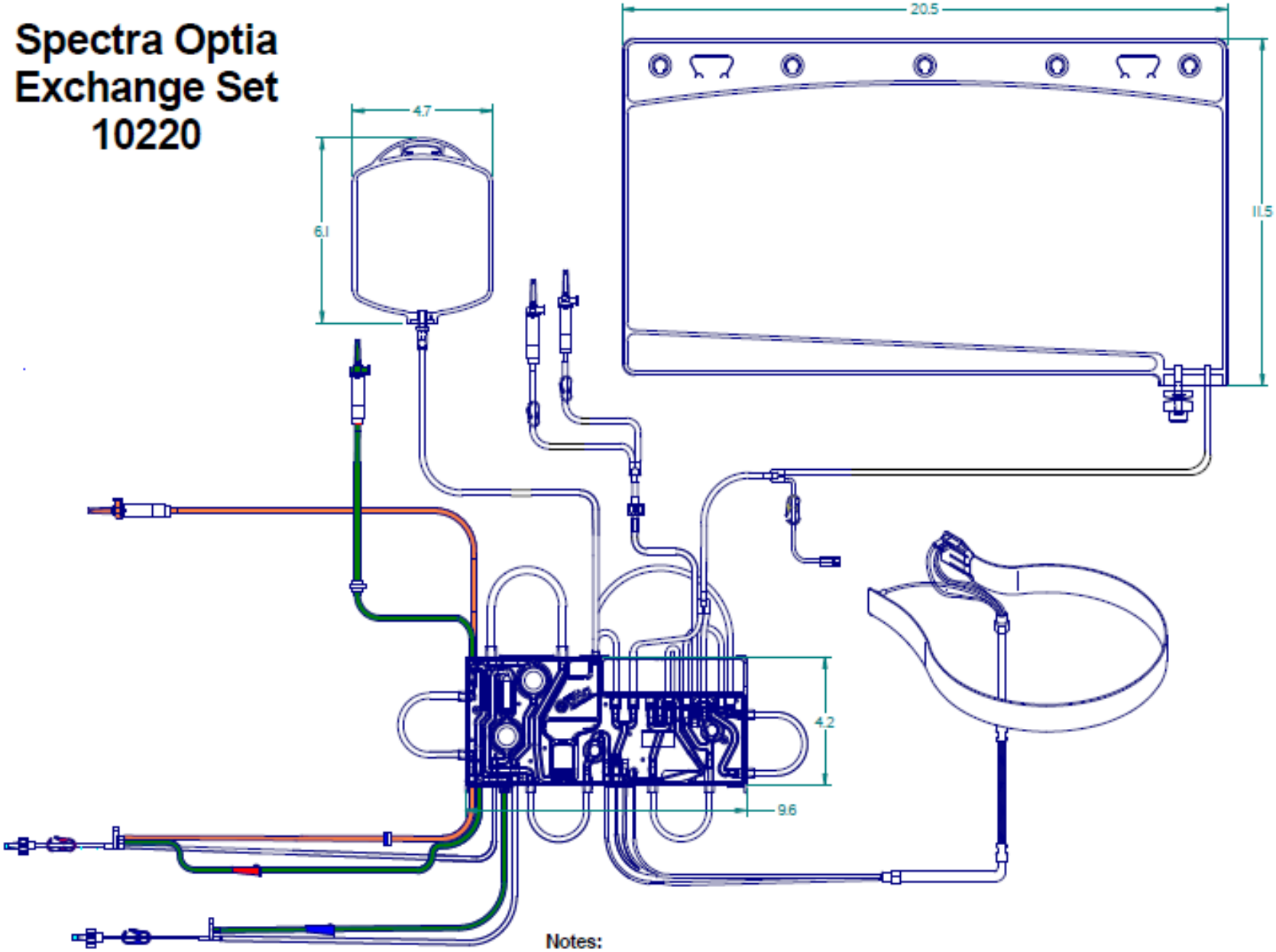
Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

Attachment 11.1
Drawing
Spectra Optia Exchange Set
(Catalog #10220)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Spectra Optia Exchange Set 10220



Notes:
1. Tube lengths and other non-dimensioned components may not be shown to scale.
2. Dimensions are shown in inches.

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12. Substantial Equivalence Discussion

12.1 Device/ Manufacturer Identification

Terumo BCT, Inc. is the manufacturer and distributor of the Spectra Optia Apheresis System. The classification information for the new device is summarized in **Table 1**.

Table 1: Device/Manufacturer Information

Device/ Manufacturer Information	
Common Name:	Therapeutic Apheresis System
Trade Name:	Spectra Optia® Apheresis System
FDA Device Classification Name:	Separator, Automated, Blood Cell and Plasma, Therapeutic
Device Class: **Review Panel:** **Product Code:**	Unclassified Gastroenterology/Urology LKN
Applicable Special Controls:	None
Intended Use:	Red Blood Cell Exchange
Manufacturer and Address of Manufacturing Facility:	Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood, CO 80215-4415

12.2 Legally Marketed Predicate Devices

As referenced below in **Table 2**, the predicate device for the Spectra Optia system RBCx protocol is the COBE Spectra (formerly known as the IBM 8400 Automated Blood Cell Separator) cleared via **K831004**. This 510(k) notification was submitted to FDA by International Business Machines (IBM) Corporation and was cleared for the conduct of therapeutic apheresis procedures. K831004 describes a broad range of therapeutic apheresis procedures, including ***Red Blood Cell Exchange***. Terumo BCT (formerly COBE Laboratories, Inc.) purchased this device from IBM and, subsequently commercialized the device as the COBE Spectra Apheresis System.

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Table 2: Device Summary

	Device Name	510(k) No.	Clearance Date
Subject Device	**Spectra Optia Apheresis System**		
Predicate Device	**IBM 8400 / COBE Spectra Apheresis System**	K831004	09/12/1983

12.3 Device Comparison

Key similarities between the RBCx protocols for the Spectra Optia and COBE Spectra are summarized below in **Table 3.** A comparison of system specifications and technology is provided in **Table 4.** The content of both tables demonstrates that the Spectra Optia system is equivalent to its legally marketed predicate device (COBE Spectra), with respect to intended use, essential technology, and clinical performance. The differences between the Spectra Optia and COBE Spectra systems are primarily based on new implenetation of advances in computer technology, channel technology, and automation of the system interface.

Table 3: Key Similarities: Red Blood Cell Exchange Conducted on the Spectra Optia and COBE Spectra Systems

	Spectra Optia system (Subject Device)	COBE Spectra system (K831004)
Intended Use	Therapeutic Plasma Exchange and **Red Blood Cell Exchange**	Multiple therapeutic apheresis procedures, including **Red Blood Cell Exchange**
Essential Technology	Both the Spectra Optia and COBE Spectra systems are automated blood cell separators achieving their essential function (the separation of blood cells and plasma) through centrifugation.	
Software	Software algorithms underlying the red blood cell exchange procedures on both the Spectra Optia and COBE Spectra systems are controlled by the same equations.	
Performance	In both a “simulated-use” laboratory validation study and human clinical trial, Spectra Optia’s RBCx protocol was found to perform the same as the COBE Spectra RBCx protocol, with respect to the system’s ability to achieve patient hematocrit targets and to maintain patient fluid balance.	

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Table 4: Technological Comparison of Spectra Optia and COBE Spectra systems

Attribute	**Spectra Optia Apheresis System (Subject Device)**	**COBE Spectra Apheresis System (Predicate Device)**
RBCx Hematocrit Accuracy	Median difference: 0.565 units 95% CI: 0.3-0.9	Median difference: 1.000 units 95% CI: 0.-3.0
RBCx Fluid Balance Accuracy	Median: 1.15 95% CI: 0.4-1.6	Median: 1.4 95% CI: 0.3-3.2
Separation Technology	Continuous flow centrifuge, based on One-Omega, Two-Omega Loop Technology	Continuous flow centrifuge, based on One-Omega, Two-Omega Loop Technology
Channel Technology	Single-stage	Dual-stage and Single-stage
Control Mechanisms		
Interface Management	Automatic	Manual
Mechanical Features		
Drive Train	Gear train	Gear train
Pump/Valve Technology	Peristaltic pumps and rotary valves	Peristaltic pumps and rotary valves
Sensor Technology	□ Access Pressure □ Return Pressure □ Centrifuge Pressure □ AC Bubble Detector □ Basin Leak □ RBC Detector □ Door Latch □ Ultrasonic Level Detector	□ Access Pressure □ Return Pressure □ Centrifuge Pressure □ AC Bubble Detector □ Basin Leak □ RBC Detector □ Door Latch □ Ultrasonic Level Detector
Filtration	□ Sterile Barrier Filters on ACDA and Saline Lines □ Filters in the Inlet and Return Lines	□ Sterile Barrier Filters on ACDA and Saline Lines □ Filters in the Inlet and Return Lines

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Disposables		
Blood-contacting Materials	Biocompatible, same materials as used in other previously cleared Terumo BCT disposables	Biocompatible, same materials as used in other previously cleared Terumo BCT disposables
Software		
User Interface Type	Graphical User Interface	Text-based LED Display
Software & Electronics Architecture	Independent Control and Safety Systems, using two microprocessors	Independent Control and Safety Systems, using eight microprocessors
Electronics		
CPU's	Pentium Class	Microprocessors
Enclosures	E-box – Isolates EMI, etc.	E-box – Isolates EMI, etc.
Communications	Ethernet	Serial

12.4 Safety and Effectiveness / Substantial Equivalence

Pre-Clinical Testing Summary

A laboratory-based, comparative study of the COBE Spectra and Spectra Optia systems was performed to demonstrate the equivalence of Red Blood Cell Exchange procedures conducted on the subject and predicate device platforms.

The results of the study's primary outcome measure demonstrated that the Spectra Optia system achieved target hematocrits more accurately than did COBE Spectra. The (statistically significant) median difference between the targeted and measured hematocrits was .56 hematocrit units for the Spectra Optia system vs. 1 hematocrit unit for the predicate COBE Spectra device. For the study's secondary outcome measures (fluid balance, hemolysis, and procedure time), the two platforms performed essentially the same. No significant hemolysis was detected for Spectra Optia, even when day-old sickle-cell waste products or 42-day-old stored red blood cells (RBCs) were processed. Finally, procedure or "run" times were similar between the two devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Testing Summary

The Evaluation of the Spectra Optia Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease (ESSENTIAL) study was conducted to validate the Spectra Optia RBCx protocol.

Results: The ESSENTIAL study successful met its primary endpoint by demonstrating that the ratio of actual to predicted fraction of cells remaining following the RBCx procedure (0.92,) was well within the pre-specified boundaries. The 95% CI (0.883, 0.963) demonstrates that the system is functioning as intended and all secondary efficacy endpoints were met. Additionally, there were reports of patients experiencing SAEs, UADEs, or patients who withdrew from the procedure or treatment due to an AE.

Conclusion: The Spectra Optia Apheresis System performs safely and effectively for the conduct of RBCx procedures in adults and children with Sickle Cell Disease.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13 Labeling

Please note that since the Spectra Optia System was first cleared by FDA (K071079), the system's instructional manual has been reorganized. As currently formatted, the system's *Essentials Guide* contains general information that is applicable to all of the system's therapeutic protocols. Individual *Procedure Guides* complement the *Essentials Guide* and provide protocol-specific instructions.

The following labeling for the Spectra Optia system RBCx protocol is provided for review:

13.1 RBCx Procedure Guide

Provided in **Attachment 13.1** is the draft Spectra Optia Red Blood Cell Exchange (RBCx) Procedure Guide. The procedure guide includes the proposed indicates for use statement for the RBCx protocol.

13.2 Operator's Manual

Provided in **Attachment 13.2** is the current Spectra Optia Essentials Guide. No changes were made to accommodate RBCx procedures.

13.3 Instructions For Use – Exchange Set

Provided in **Attachment 13.3** is the current Instructions for Use for the Spectra Optia Exchange Set (#10220). Copies of the kit and case labels for the Exchange Set are provided in **Attachments 13.4** and **13.5**, respectively.

13.4 RBCx Brochure

Provided in **Attachment 13.6** is a draft copy of the marketing brochure for the RBCx protocol.

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Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

Attachment 13.1

Draft Red Blood Cell Exchange Procedure Guide

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DRAFT

Spectra Optia®

Apheresis System

TERUMOBCT
Unlocking the Potential of Blood

RBCX

Red Blood Cell Exchange (RBCX) Procedure Guide

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DRAFT

Spectra Optia® Apheresis System

Red Blood Cell Exchange (RBCX) Procedure Guide

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Spectra Optia® Apheresis System machine and disposable sets may be covered by one or more of the following patents:

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Germany: 69618453, 69820404, 69308441, 69313212, 69634860, 69733198, 69926313, 69434848, 69434864, 69636518, 69604578, 69605901

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Preface

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About This Guide

This guide contains instructions for performing Red Blood Cell Exchange (RBCX) procedures on the Spectra Optia Apheresis System. Use this guide in conjunction with the *Spectra Optia Apheresis System Essentials Guide* when performing procedures on the system.

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Spectra Optia Apheresis System

Intended Use

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications. The system may be used to perform the following procedures:

- Therapeutic Plasma Exchange (TPE)
- Red Blood Cell Exchange, Depletion, and Depletion/Exchange (RBCX)

Indications for Use

The Spectra Optia Apheresis System, a blood component separator, can be used can be used to perform Red Blood Cell Exchange (RBCX) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Contraindications for Use

There are no known contraindications for use of the Spectra Optia system except those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

Warnings and Cautions for Use

Below is a list of warnings and cautions that apply to the use of the Spectra Optia system when performing RBCX procedures. See the *Spectra Optia® Apheresis System Essentials Guide* for a complete list of warnings and cautions that apply to the use of the system and the Seal Safe system. Although this information may also appear in other sections of the guides, the operator should read and understand the information listed in both publications before using the system.

Warnings for use

Procedural warnings

1 Follow standard transfusion practices for cellular components during RBCX procedures.

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2 Platelets are removed with Red Blood Cells during an RBCX procedure. The approximate percent of Platelets removed depends on the number of total blood volumes (TBV) processed, as shown in the table below. It is the physician's responsibility to determine the appropriate treatment for the patient.

TBV Processed	Platelets Removed (Approximate%)
0.5	39
1.0	63
1.5	78
2.0	86

3 It is advisable to obtain the patient's detailed drug history before each apheresis procedure. For those drugs potentially affected by apheresis procedures, the physician should either adjust the doses or give the medications immediately after the procedure.

4 The operator must verify the correct input of information relevant to the safety of each apheresis procedure.

5 When preparing to perform a procedure, ensure that the lines are connected to the correct fluids, and that fluid is flowing into the drip chambers:

- AC line (orange) to the anticoagulant container
- Saline line (green) to the normal saline (0.9%) container

6 Check that the tubing is correctly loaded in all pumps before starting a procedure. Visually inspect each pump to ensure that tubing does not protrude.

7 Before starting a procedure, inspect all lines, especially those in the centrifuge and on the front panel to ensure they are not obstructed. Tubing that is occluded or mechanically constrained can lead to malfunction or fluid imbalance. Inlet and return lines perform without difficulty as long as the interior diameter of the tubing is larger than the interior diameter of the patient's inlet and return access.

8 Only blood or blood products should be processed in the centrifuge.

9 Do not connect the patient before the system instructs you to do so.

10 Rigorous attention should be paid to proper venipuncture site selection and decontamination.

11 If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

12 Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

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13 Before connecting the patient, ensure that the AC line contains anticoagulant at the inlet manifold.

14 The inlet and return pressure sensors are not intended to detect infiltrations of the vein. Monitor the patient for infiltrations.

15 Tubing sets may occasionally fail, which could result in the loss of blood, blood products, or the introduction of air into the tubing set. It is very important that the operator watch for leaks in the cassette, all tubing and welds, and in the channel while the set is in use. Operators should take adequate precautions in handling blood and blood products in accordance with their facility's standard operating procedures.

16 When handling extracorporeal blood circuits, take adequate precautions to prevent the possible exposure to and transmission of infectious diseases.

17 The following can cause fluid imbalance:

- Administration of replacement fluid that is not at room temperature during a procedure
- Use of improperly vented fluid containers
- Equipment malfunction
- Improperly clamped or closed lines, or improperly loaded valves
- Use of inadequately primed or clotted filters on the replace line of the Exchange Set
- Tubing that is incorrectly loaded in the pumps

18 Terumo BCT does not recommend performing rinseback during RBCX procedures. The data the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

19 Do not touch **Unload** to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

Solution and medicinal fluid warnings

20 When using biologically-derived replacement fluids, closely monitor the patient for reactions.

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Cautions for use

Procedural cautions

21 The Spectra Optia system has many safety features. However, a patient reaction can occur rapidly. Therefore, it is imperative that the operator monitor the patient and the system throughout the procedure.

22 The physiological condition of patients may affect the outcomes of procedures performed on the Spectra Optia system.

23 Patients with impaired or abnormal citrate metabolism (for example, if the patient has liver or renal disease) may present an increased risk of citrate sensitivity. Attending physicians should assess the appropriateness of such patients for apheresis procedures and prescribe how they should be monitored during procedures.

24 Use aseptic technique throughout all procedures to ensure patient safety and product quality.

25 Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit. The attending physician is responsible for prescribing the anticoagulant used, however, and all personnel involved in performing apheresis procedures should read the anticoagulant manufacturer's product insert before use.

26 The higher the inlet:AC ratio used during the procedure, the greater the risk is for aggregates and clumps to form in the tubing set.

27 For patient comfort and optimal system operation, be sure that the fluids used during the procedure are at room temperature before connecting them to the tubing set.

28 Do not connect the fluids to the tubing set before the system instructs you to do so.

29 To avoid a failed test of the tubing set, do not raise and lower the cassette after there is fluid in the set.

30 If you leave the roller clamp on the saline line completely open when the patient is connected, you will quickly infuse a large amount of saline to the patient.

31 All used disposable materials should be considered hazardous, and should be handled and disposed of at the end of the procedure in accordance with all applicable regulations.

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General tubing set cautions

32 The tubing set is intended for single-use only to ensure sterile tubing conditions. Do not resterilize the set.

33 The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:

- Severe kinks in the tubing are apparent.
- The tubing set appears to be incorrectly assembled.
- The tubing set is damaged.
- Any clamps are closed on the lines.

34 You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.

35 Do not stretch the tubing when folding the channel to install it in the centrifuge to avoid damaging the tubing set.

36 Use only your fingers to load the channel into the filler. To avoid puncturing the channel, never use a sharp object.

37 Do not seal the inlet line of the four-lumen tubing. Sealing the line could cause the tubing set to fail when you raise the cassette to unload the set.

38 Ensure all luer connections are secure.

Exchange Set cautions

39 Do not use the Exchange Set if the end caps are not in place.

40 Leave the cap on the unused luer (on the remove bag) to prevent fluid leakage. Ensure the cap fits tightly.

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Replacement Fluids Administered During RBCX Procedures

The physician is responsible for prescribing the replacement fluids for the RBCX procedure. The prescription should consider patient fluid status and other pertinent factors the physician believes may impact the patient's condition.

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Configuration and Procedure Data Management

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Configuring the Spectra Optia System

The Spectra Optia system allows you to configure procedure-independent and procedure-specific operating parameters to meet your facility's requirements. Configuration settings for the procedure-independent parameters apply to all procedures. Configuration settings for procedure-specific parameters apply to only the specified procedure type. Several parameters have a default setting. The system uses the default setting unless you enter a different setting. You must touch **Confirm** after you finish configuring the parameters in order for the settings to take effect.

To configure the parameters, perform the following steps:

1. Touch the **Config** menu button. The configuration tabs appear.
2. Touch the tab for the parameters that you want to configure. The corresponding configuration screen appears.
3. Touch the button for the parameter that you want to configure:
   - For parameters with only two settings, toggle between the settings until the setting that you prefer appears on the button.
   - For parameters with more than two settings, a list appears to enable you to select a setting.
   - For parameters that require a numeric setting, a data entry pad appears to enable you to enter a number. The range of acceptable values appears on the data entry pad.
4. Repeat step 3 until you finish configuring the parameters.
5. Touch **Confirm**.

Configuring Procedure-Independent Operating Parameters

See the *Spectra Optia® Apheresis System Essentials Guide* for instructions on configuring procedure-independent operating parameters.

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Configuring Procedure-Specific Operating Parameters

You may configure procedure-specific operating parameters after you select the procedure and before you connect the patient. The only configuration settings that you can change during the run are the inlet pressure and return pressure alarm limits.

RBCX operating parameters

Touch the **RBCX** tab to access the RBCX procedure configuration screen. Table 2-1 shows the parameters and setting options to configure on this screen.

Table 2-1: RBCX procedure configuration parameters and setting options

Parameter	Description	Setting Options
Maximum AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The rate configured represents the maximum rate at the start of the procedure.	0.8 to 1.2 (Default is 0.8)
Inlet:AC ratio (__:1)	Ratio of the inlet flow rate to the AC flow rate. The ratio configured represents the ratio at the start of the procedure.	6.0 to 15.0 (Default is 13.0)
Pressure alarm limit: Inlet (mmHg)	Limit at which an inlet pressure alarm occurs	-100 to -250 (Default is -250)
Pressure alarm limit: Return (mmHg)	Limit at which a return pressure alarm occurs	200 to 400 (Default is 400)
Custom prime recommendation (% TBV)	Percent of TBV or RBC in mL in the tubing set at which the system prompts you to consider performing a custom prime	• 10 • 15 (Default is 15)
Custom replacement fluid (%)	Percent of citrate in the custom replacement fluid	0 to 25 (Default is 0)
Fluid balance limit (% TBV)	Percent of total blood volume (TBV) in mL used to calculate the upper and lower caution limit for fluid balance. For example, if the patient has a TBV of 4 L and the limit is set at 10%, the system will notify you if the fluid balance exceeds +/- 400 mL.	5 to 15 (Default is 5)

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Blood warmer operating parameters

Touch the **Blood Warmer** tab to access the blood warmer configuration screen. Table 2-2 shows the parameters and setting options to configure on this screen.

Table 2-2: Blood warmer configuration parameters and setting options

Parameter	Description	Settings Options
Return line	Indicates if a blood warmer is connected to the return line. The system will instruct you when to connect the blood warmer tubing set before you connect the patient.	• Yes • No (Default is No)
Tubing volume (mL)	Volume of the blood warmer tubing set on the return line. The system uses this information to adjust the calculation for the extracorporeal volume, minimum volume required for a custom prime, and volume of saline required for rinseback.	1 to 100 (Default is 40)
Replace line	Indicates if a blood warmer is connected to the replace line during a procedure using an Exchange Set.	• Yes • No (Default is No)

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Entering Data During the Procedure

The Spectra Optia system requires that you enter specific data, such as fluid data, during an RBCX procedure. You may also change numerical values for certain operating parameters as you monitor the run. Table 2-3 shows data entry ranges for the parameters according to the screen on which the data entry buttons appear. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad also displays the established range for the parameter, or the calculated range if the range adjusts based on related data.

Table 2-3: Data entry ranges for RBCX procedure parameters

Screen	Parameter	Range
Patient data	Height: • ft • in • cm	• 1 to 8 • 12 to 96 • 30 to 244 (Value entered cannot be changed after run starts.)
	Weight: • lb • kg	• 5 to 500 • 2 to 227 (Value entered cannot be changed after run starts.)
	Hct (%)	10 to 80 (Value entered cannot be changed after run starts.)
	TBV (mL)	300 to 15000 (Value entered cannot be changed after run starts.)
Fluid data	Replacement fluid Hct (%)	10 to 80
	Fluid balance (mL or %)	-25% of TBV + suggested rinseback volume to +25% of TBV (Caution status applies if entry exceeds configured limit)

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Table 2-3: Data entry ranges for RBCX procedure parameters (continued)

Screen	Parameter	Range
Custom prime data entry	RBC unit Hct (%)	25 to 80
	Maximum inlet flow rate (mL/min)	5.0 to 120.0
	Volume (mL)	100 to 400
Main run	Maximum inlet flow rate (mL/min)	5.0 to 142.0
	Replace volume (mL)	10 to 10000
	Maximum AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2.0 to 50.0 (Warning appears if entry exceeds 15.0.)
Exchange status	Current patient Hct (%)	10 to 80
Bolus	Volume (mL)	From 10 to an amount based on hypervolemia limit of 25% of TBV
	Flow rate (mL/min)	10.0 to 120.0
Run values	Maximum AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2.0 to 50.0 (Warning appears if entry exceeds 15.0.)
	FCR (%) • Starting defective RBC (%) • Target defective RBC (%)	1 to 99 • 10 to 100 • 1 to 99 (Adjusts based on starting defective RBC entered.)
	Minimum Hct (%)	20 to current patient Hct minus 2 (Could be lower if patient has a small TBV.)
	Target Hct (%)	20 to 60

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Table 2-3: Data entry ranges for RBCX procedure parameters (continued)

Screen	Parameter	Range
	Replaced (mL): Exchange	10 to 10000
	Maximum inlet flow rate (mL/min)	5.0 to 142.0
Options	Blood warmer: Tubing set volume (mL)	 1 to 100 (Default volume is 40.)
Rinseback	Return flow (mL/min)	2.0 to 100.0
Run targets	Target Hct (%)	20 to 60
	FCR (%)	1 to 99
	Replaced (mL): Exchange	10 to 10000

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Performing a Red Blood Cell Exchange (RBCX) Procedure

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RBCX Procedure Types

The Spectra Optia system can be used to perform the following types of Red Blood Cell Exchange (RBCX) procedures:

- Exchange
- Depletion/Exchange
- Depletion

During an exchange procedure, the system removes defective RBC from the patient and replaces them with healthy donor RBC. During a depletion procedure, the system removes excess or defective RBC from the patient and replaces them with desired replacement fluid. A depletion/exchange procedure consists of a depletion procedure followed by an exchange procedure.

Follow the instructions on the screens and in this chapter to select a Red Blood Cell exchange (RBCX) procedure and then the type of exchange you want to perform.

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Functional Description of an RBCX Procedure

There are three main phases of operation during an RBCX procedure: Centrifuge ramp phase, depletion phase and exchange phase. The centrifuge ramp phase occurs during each RBCX procedure. The type of procedure you select determines whether a depletion or an exchange phase occurs. The phases of operation begin after the system pumps the patient's blood into the channel of the tubing set at the start of the run.

Centrifuge ramp phase

During the centrifuge ramp phase, the system increases the centrifuge speed to the rpm required for removing RBC from the channel. This phase occurs at the start of the run, after the system decreases the speed or stops the centrifuge due to an operating condition or alarm, or any time a faster speed is required, such as after a significant increase in the inlet pump flow rate.

Depletion phase

The depletion phase occurs during a depletion or depletion/exchange procedure. During a depletion phase, RBC exit the channel to the remove bag. The system returns Plasma and replacement fluid. This phase starts when the centrifuge ramp phase is complete and ends when the target Hct (depletion procedure) or minimum Hct (depletion/exchange procedure) has been attained.

Exchange phase

The exchange phase occurs during an exchange or depletion/exchange procedure. During an exchange phase, the RBC exit the channel to the remove bag and the system returns Plasma and replacement RBC to the patient. This phase starts when the centrifuge ramp phase (exchange procedure) or initial depletion procedure (depletion/exchange procedure) is complete and ends when the target FCR (fraction of cells remaining) or target volume of replacement RBC has been attained.

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Preparing to Perform the Procedure

Supplies

Assemble the following supplies before you begin an RBCX procedure:

- Spectra Optia Apheresis System
- Spectra Optia Exchange Set
- 0.9% sodium chloride injection USP
- Anticoagulant ACD-A
- Replacement fluid prescribed by the patient's physician
- If using peripheral access:
  - Two needles of sufficient gauge to accommodate the procedure flow rate
  - Supplies for preparing the venipuncture site
  - Blood pressure cuff
- If using a vascular access device:
  - Supplies to disinfect, aspirate from, and connect to the device according to your standard operating procedures

Optional supplies:

- Filters for replacement fluid
- Supplies for collecting blood samples
- Apheresis procedure record

Selecting the Procedure

Perform the following steps to select an RBCX procedure. Then follow the steps on the screens and in this guide to enter the required patient and procedure data, and to select the type of RBCX procedure you want to perform.

1. Touch **Select Procedure**. The procedure selection screen appears.
2. Touch **Red Blood Cell Exchange (RBCX)**.
3. Touch **Confirm**. The system loads the procedure software and returns to the prepare procedure screen.

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Loading and Priming the Tubing Set

Follow the instructions on the screens and in the *Spectra Optia® Apheresis System Essentials Guide* to load, test, and prime the tubing set.

Navigating the RBCX Procedure Screens

Table 3–1 shows the menu buttons and menu tabs to use to navigate the screens during an RBCX procedure. Menu buttons and tabs are active depending on the current operating state.

Table 3–1: Menu buttons and tabs on RBCX procedure screens

Config	Data	Run	End Run
System	Patient Data	Exchange Status	Rinseback
Report	Fluid Data	Operation Status	Disconnect
RBCX	Alarm History	Bolus	Run Targets
Blood Warmer	Report	Strobe	
		Run Values	
		Options	

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Entering and Confirming Patient and Procedure Data

This section contains instructions for entering the patient data, selecting the exchange type, entering the fluid data, and entering and confirming the target values and run values. You can enter the data after you select the procedure and before you connect the patient.

Entering the Patient Data

Note: When you must enter numerical data, the system displays a data entry pad to enter the number. The acceptable numerical range appears on the data entry pad.

1. Touch the buttons on the screen to enter the following patient information:
   - Sex
   - Height
   - Weight
   - Hematocrit (Hct)
2. The Spectra Optia system uses the sex, height, and weight to calculate the patient's total blood volume (TBV), according to the formula described in Table 3–2. To change the TBV, touch **TBV** and enter a different volume.

   Note: The system cannot calculate an accurate TBV for patients that weigh less than 25 kg (approximately 55 lb).

   If the patient weighs less than 25 kg (approximately 55 lb), the system does not display a TBV. You must calculate and enter the appropriate TBV for the patient.
3. Touch **Confirm**. The fluid data screen appears.

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Table 3–2: Formula for calculating TBV (mL) using data in metric and English units

Metric		
	Female	183 + [356 x height^3 (meters)] + [33.1 x weight (kg)]
	Male	604 + [367 x height^3 (meters)] + [32.2 x weight (kg)]
English		
	Female	183 + [0.005835 x height^3 (inches)] + [15 x weight (lb)]
	Male	604 + [0.006012 x height^3 (inches)] + [14.6 x weight (lb)]

Source:

Allen TH, et. al. Prediction of blood volume and adiposity in man from body weight and cube of height. Metabolism 1959;39:307.

Nadler SB, et al. Prediction of blood volume in normal human adults. Surgery 1962;51:224-32.

Selecting the Exchange Type

The default exchange type is “Exchange” and appears on the button for the exchange type when the screen appears. To select a different exchange type, perform the following steps:

1. Touch **Exchange**. The following list of exchange types appears:
   - Exchange
   - Depletion/Exchange
   - Depletion
2. Select the exchange type by touching the corresponding button on the screen.

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Entering the Fluid Data

The fluid data buttons are enabled or disabled according to the exchange type you select. Perform the steps below to enter the fluid data and fluid balance.

Selecting the type of replacement fluid

Depletion:

1. Touch **Fluid Type**. A list of replacement fluid types to use for the depletion appears.
2. Select one of the following fluid types by touching the corresponding button on the screen:
   - Saline/Albumin
   - Plasma
   - Custom

Exchange:

1. Touch **Fluid Hct**. The data entry pad appears.
2. Enter the average Hct (%) of the replacement fluid for the exchange.

Note: The system uses data you enter, including the Hct of the replacement fluid, to determine when the target Hct has been attained. It is important that you enter an accurate Hct for the replacement fluid.

Entering the fluid balance

Note: The fluid balance includes fluid administered and removed during the entire procedure, but does not include fluid bolus volume.

1. The Spectra Optia system allows you to enter the fluid balance desired for the patient to have at the end of the procedure. To enter the fluid balance, do one of the following:
   - To enter an amount in mL, touch **Volume** and use the data entry pad to enter a negative or positive volume. The system will calculate and display the corresponding percent.
   - To enter an amount in percent, touch **Percent** and use the data entry pad to enter a percent. The system will calculate and display the corresponding volume.
2. Touch **Confirm** to save the fluid data. The run values screen appears.

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Entering and Confirming Run Targets and Run Values

Note: You may also access the run values screen by touching **View/Change Run Values** on the procedure data screen.

Enter the target values listed below, according to the type of RBCX procedure you selected. Table 3-3 contains descriptions of run targets that appear on the run values screens. Then review the run values on the screen and make any changes necessary to achieve your run targets.

Exchange procedures

- Target Hct (%)
- One of the following:
  - Replaced: Exchange (mL)
  - FCR (%)

Depletion/Exchange procedures

- Minimum Hct (%)
- Target Hct (%)
- One of the following:
  - Replaced: Exchange (mL)
  - FCR (%)

Depletion procedures

- Target Hct (%)

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Table 3-3: Descriptions of run targets for RBCX procedures

Run Target	Description
FCR (%)	Fraction of cells remaining. Desired percent of starting defective RBC remaining in the patient's blood at the end of the procedure. (Desired defective cells (%)/starting defective cells (%) = FCR.) After you enter an FCR for an exchange procedure, the system calculates and displays the volume of replacement fluid required to complete the procedure. **Note:** You may enter the starting and target defective RBC instead of the FCR, and the system will calculate and display the FCR. To do this touch the button for FCR on the screen and then touch **FCR** on the data entry pad. The icon appears on the data entry pad to indicate you have entered the values for defective RBC.
• Starting defective RBC (%)	Percent of defective RBC in the patient's blood at the start of the procedure
• Target defective RBC (%)	Percent of the defective RBC in the patient's blood at the end of the procedure
Minimum Hct (%)	Lowest patient Hct during the procedure.
Target Hct (%)	Desired patient Hct at the end of the procedure
Replaced (mL): Exchange	Volume of replacement fluid that is required to complete the exchange procedure. If you enter a volume here, the system calculates and displays the FCR.

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Perform the following steps to enter and confirm the run targets and run values:

1. Touch the button on the screen that corresponds to the target value you want to enter. The data entry pad appears.
2. Enter the target value.
3. Review the run values that appear on the screen to ensure that they are correct.

   Note: During depletion/exchange procedures, the system displays the run time for the depletion in parenthesis above the total run time for the depletion/exchange.

   If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

   Note: Only the color of the last value you changed remains yellow. The values you previously changed will change back to white.

4. Touch **Confirm**.

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Starting the Procedure

1. Follow the instructions on the screen to perform the following steps:
   a. Empty the saline drip chamber.
   b. Rehang the saline container.
2. Touch **Confirm**.
3. If you are using a blood warmer on the replace line, perform the following steps to connect and prime the blood warmer tubing set, and prime the replace line:
   a. Disconnect the replace line from the spikes at the luer connector below the manifold.
   b. Clamp one end of the blood warmer tubing set.
   c. Connect the blood warmer tubing set to the spikes at the luer connector below the manifold.
   d. Spike the replacement fluid and squeeze the drip chamber.
   e. Unclamp the line to the second spike to prime both lines and fill the second drip chamber.
   f. Reclamp the line to the second spike.
   g. Unclamp the blood warmer tubing set and prime the tubing set.
   h. Reclamp the blood warmer tubing set.
   i. Connect the blood warmer tubing set to the luer connector on the replace line.
   j. Put the segment of the replace line that is between the manifold and the luer connector in the replacement fluid detector. The luer connector must be positioned below the replacement fluid detector.

   Note: Ensure that you position the luer connector below the replacement fluid detector. If the blood warmer tubing set is not positioned below the fluid detector, you must reprime the tubing set if the replacement fluid container runs dry during the procedure.
4. If you are not using a blood warmer on the replace line, perform the following steps to prime the replace line:
   a. Spike the replacement fluid and squeeze the drip chamber.
   b. Unclamp the second replace line to prime the lines and fill the second drip chamber.
   c. Reclamp the line to the second replace line.
   d. Put the replace line into the replacement fluid detector.
5. Touch **Continue**.

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6 Follow the instructions on the screen to do the following. Be sure to perform these steps in the order that appears on the screen:

a. If you are using a blood warmer on the return line, connect the blood warmer tubing set to the line.

b. Prime the inlet line and the return line. If you are using a blood warmer, prime the blood warmer tubing set.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

c. Clamp the inlet line and the and return line.

d. Close the inlet saline line and return saline line.

7 Touch **Confirm**. The connect patient screen appears.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions on the screen to perform the following steps:

a. Connect the patient.

b. Unclamp the inlet and return lines.

2 Touch **Start Run**. The system primes the replace line with replacement fluid, and then begins drawing the patient's blood into the tubing set. The main run screen appears.

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Monitoring the Run

This section contains descriptions of run screens that help you monitor the progress of the run. To access these screens, touch the **Run** menu button and then the tab for the screen you want to view. Ensure you verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and the bags.

Main Run Screen

The main run screen is the default run screen, and displays or provides access to the information that you are most likely to need to monitor the procedure. If you want to return to the main run screen after viewing a different screen during the run, touch the go back button, the active menu button, or the tab for the current screen. Figure 3-1 shows an example of the main run screen for a depletion/exchange procedure.

Figure 3-1: Example of the main run screen for a depletion/exchange procedure

Run time bar graph

Touch the hourglass icon to view the elapsed run time, the remaining run time, and the total run time. Touch the clock icon to view in clock time the starting run time, the current time, and the ending run time. If you are performing a depletion/exchange procedure, a yellow mark appears on the graph to indicate when the depletion phase will end.

Packing factor

Packing factor is a number that indicates how the system separates the blood in the channel to maintain a specific interface position in the connector. The current packing factor appears on the button.

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Current/target flow rate (mL/min) and volume (mL)

Touch **Current** or **Target** to toggle between the current and target views for flow rates and volumes for the AC, inlet, plasma, and replace pumps.

Remove bag (mL)

Remove bag (mL) indicates the current volume in the remove bag.

AC infusion rate

The maximum AC infusion rate (mL/min/L TBV) for the current procedure appears on the button. Touch this button to change the maximum rate (mL/min/L TBV) at which the AC from the ACD-A bag and the AC in the replacement fluid is infused to the patient.

Inlet:AC ratio

The ratio of inlet volume to AC from the ACD-A bag (__.1) for the current procedure appears on the button. Touch this button to change the inlet:AC ratio.

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Exchange Status Screen

To access the exchange status screen, touch the **Run** menu button and then touch the **Exchange Status** tab. This screen displays the current status of the exchange. Figure 3-2 shows an example of the exchange status screen for a depletion/exchange procedure.

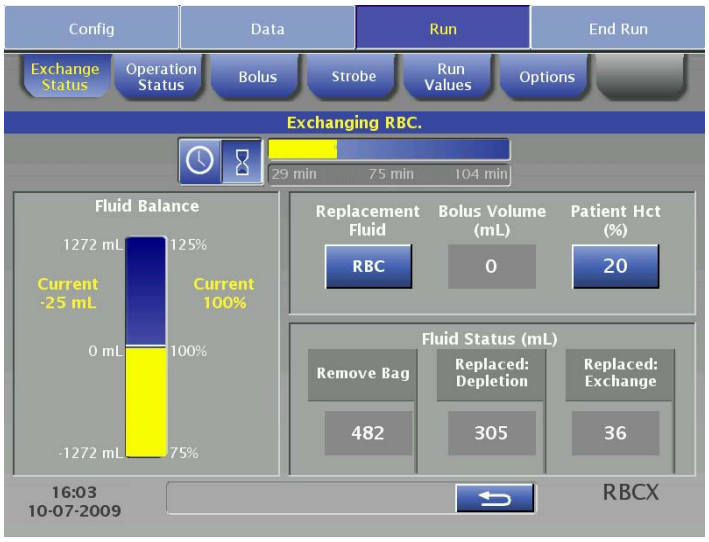

Figure 3-2: Example of the exchange status screen for a depletion/exchange procedure

Fluid balance

The graph shows the current patient fluid balance in volume (mL) and percent (%). The values at the top and bottom of the graph indicate the absolute fluid balance limits the system allows for this patient.

Replacement fluid

The type of replacement fluid currently in use appears on the button. Touch this button to select a different fluid type.

Bolus volume (mL)

Bolus volume (mL) is the cumulative volume of fluid bolus that has been given during the procedure.

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Patient Hct (%)

The current (estimated) patient Hct the system predicts appears on the button. Touch this button to change the value if it is necessary for you to remeasure the patient's Hct during the run.

Note: The system uses the patient Hct and the replacement fluid Hct that you enter before the start of the run to predict the current patient Hct. If the data entered is not correct, the prediction will not be accurate.

Fluid status (mL)

Fluid status (mL) shows the current volume in the remove bag and the volume of replacement fluid that has been used during the current procedure.

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Monitoring the Patient and Adjusting the Procedure

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the system.
2. Notify the attending physician of the patient's condition, according to your facility's standard operating procedures.
3. To reduce the symptoms and continue the run, touch **AC Infusion Rate** on the main run screen and reduce the rate to the desired value.
4. If reducing the infusion rate does not alleviate the symptoms, pause the procedure and administer appropriate medical treatment.

Giving a Fluid Bolus

Perform the following steps to give a fluid bolus:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Bolus** tab. The fluid bolus screen appears.
3. Follow the instructions on the screen to spike the saline container to the replace line. Confirm that the replace line is not clamped.
4. Touch **Volume** and enter the volume (mL) of the bolus.
5. Touch **Flow Rate** and enter the flow rate (mL/min) for the bolus.

Note: If the fluid you use for the bolus is a blood product, enter a flow rate in accordance with your local transfusion practices.

6. To begin the bolus, touch **Start Bolus**. The system delivers the bolus.

   The screen displays the progress of the bolus. To cancel the bolus before delivery is complete, touch **Cancel Bolus**.
7. When the bolus is complete, the system pauses. Touch **Continue** to resume the procedure.

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Changing the Type of Replacement Fluid

Perform the following steps to change the type of replacement fluid during the run:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Fluid Data** tab. The fluid data screen appears.

Note: To reach the fluid data screen from the exchange status screen, touch the button for replacement fluid.

3. Change the type of replacement fluid.
4. Touch **Confirm**.The run values screen appears.
5. Review the run values.
6. Touch **Confirm**.

Changing the Fluid Balance

Perform the following steps to change the fluid balance:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Fluid Data** tab. The fluid data screen appears.
3. Enter the new fluid balance.
4. Touch **Confirm**. The run values screen appears.
5. Review the run values.
6. Touch **Confirm**.

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Changing the Current Patient Hct

Perform the following steps to change the current patient Hct during the run:

1. Touch the pause button to pause the pumps.
2. Measure the patient's Hct, according to your standard operating procedures.
3. Touch the **Run** menu button. The run tabs appear.
4. Touch the **Exchange Status** tab. The exchange status screen appears.
5. Touch the button for the patient Hct. The data entry pad appears.
6. Enter the current patient Hct. A screen appears to confirm the change to the Hct.
7. Follow the instructions on the screen to verify and confirm the change. The run values screen appears.
8. Review the run values.
9. Touch **Confirm**.
10. Touch the pause button to restart the pumps.

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Discontinuing or Ending the Run

Discontinuing the Run

If you decide to discontinue the run before attaining a run target, perform the following steps:

1 Touch the **End Run** menu button.

2 Do one of the following:

- To discontinue the run, touch the **Disconnect** tab and follow the instructions under "Completing the Procedure" on page 39 to complete the procedure.
- To discontinue the run and perform rinseback, touch the **Rinseback** tab and follow the instructions under "Ending the Run With Rinseback" on page 38 to complete the procedure.

Ending the Run

The run targets screen appears and the system sounds a tone when a run target has been attained. Review the run targets and decide to extend or end the run. Figure 3-3 shows and example of a run targets attained screen for a depletion/exchange procedure.

Figure 3-3: Example of a run targets attained screen for a depletion/exchange procedure

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Extending the Run

1. To extend the run, increase the value of a run target. Touch the button for the run target you want to increase and use the data entry pad to enter a new value. The run values screen appears.
2. Review the run values.
3. Touch **Confirm**. The system will continue the run. When the new target is attained, the run targets attained screen reappears and the system sounds a tone.

Ending the Run

1. Touch **Disconnect**. The confirm disconnect screen appears.
2. Touch **Proceed to Disconnect**, and then touch **Confirm**.

Ending the Run With Rinseback

Warning: Terumo BCT does not recommend performing rinseback during RBCX procedures. The data the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

1. Touch the **End Run** menu button. The end run tabs appear.
2. Touch the **Rinseback** tab. The confirm rinseback screen appears.
3. Touch **Proceed to Rinseback,** and then touch **Confirm**.
4. Follow the instructions on the screen to clamp the inlet line.
5. Touch **Continue**. The system tests the pressure in the inlet line.
6. Follow the instructions on the screen to open the inlet saline line.
7. Touch **Continue**. The rinseback status screen appears.

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Completing the Procedure

This section provides instructions on disconnecting the patient and reviewing the procedure summary data. For instructions on printing a copy of a procedure report, see the *Spectra Optia® Apheresis System Essentials Guide.*

Disconnecting the Patient

1. Follow the instructions on the screen to perform the following steps:
   a. Clamp the inlet line and return line.
   b. Disconnect the patient lines.
   c. Seal the AC line, saline line, and lines to the bags.
2. Touch **Unload**. The system confirms that the inlet and return lines are clamped, and raises the cassette. The procedure summary screen appears.

Reviewing the Procedure Summary Data

The procedure summary screens contain important data about the procedure. The screens appear at the end of the procedure after the cassette is raised. Figures 3-4 and 3-5 show example pages of the procedure summary screens. Tables 3–4 and 3–5 contain descriptions of the data that can appear on the screens.

Note: The start time and end time on the procedure summary screen are accurate to ± 1 minute.

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Procedure Summary, Page 1

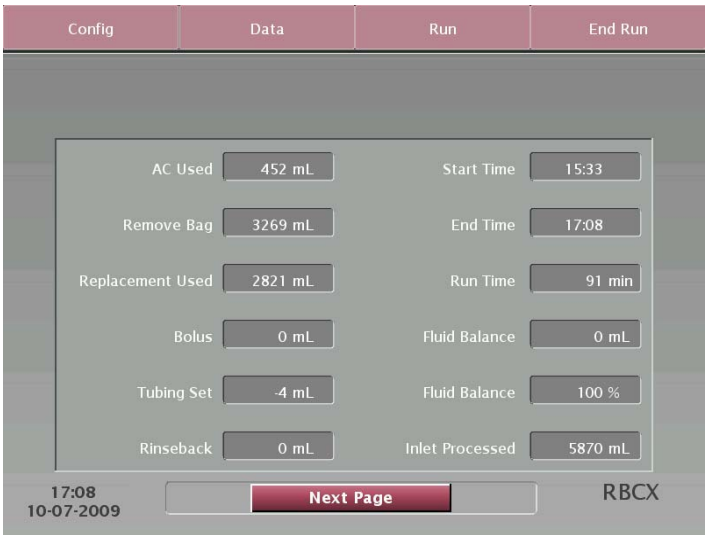

Figure 3-4: Example of page 1 of the procedure summary for all RBCX procedures

Table 3–4: Descriptions of data on page 1 of the RBCX procedure summary screens

Data	Description
AC Used	Total volume of AC used during the run
Remove Bag	Total volume of saline, AC, and blood in the remove bag
Replacement Used	Total volume of fluid the replace pump processed, not including any bolus volume
Bolus	Total volume of fluid delivered to the patient during the bolus
Tubing Set	Difference between the volume in the tubing set at the start of the run and the volume in the set at the end of the run or at the start of rinseback (negative value indicates fluid volume in the set)
Rinseback	Total volume of fluid the return pump processed during rinseback, not including any bolus volume given during rinseback
Start Time	Time when the operator touched **Start Run**
End Time	Time when the system completed the run or rinseback
Run Time	Total time the system operated the inlet pump (does not include time when the pump was paused)

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Table 3–4: Descriptions of data on page 1 of the RBCX procedure summary screens (continued)

Data	Description
Fluid Balance	Patient fluid balance (mL) at the end of the procedure (does not include fluid bolus volume)
Fluid Balance	Patient fluid balance (%) at the end of the procedure (does not include fluid bolus volume)
Inlet Processed	Total volume of fluid (includes Whole Blood and AC) the inlet pump processed during the run

Procedure Summary, Page 2

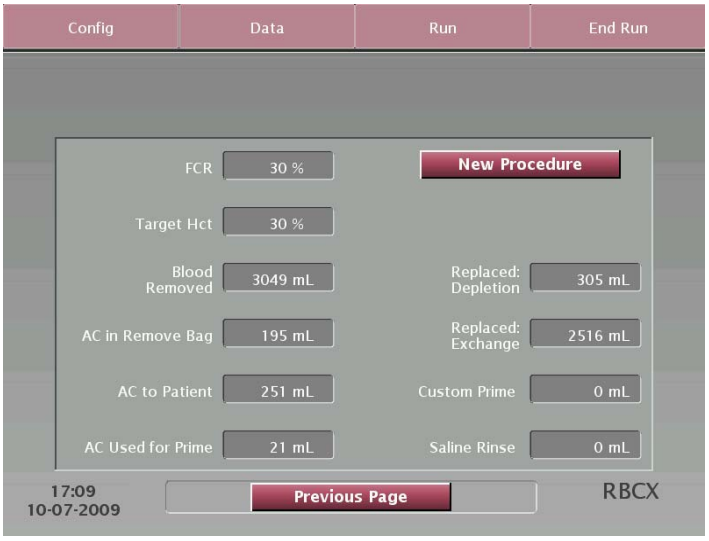

Figure 3-5: Example of page 2 of the procedure summary for a depletion/exchange procedure

Table 3–5: Descriptions of data on page 2 of the RBCX procedure summary screens

Data	Description
FCR	Percent of starting defective RBC remaining in the patient's blood
Target Hct	Predicted patient Hct at the end of the procedure
Blood Removed	Total volume of patient blood removed
AC in Remove Bag	Total volume of AC (from AC bag) in the remove bag
AC to Patient	Total volume of AC (from AC bag) the patient received
AC Used for Prime	Volume of AC (from AC bag) used for the saline prime

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Table 3–5: Descriptions of data on page 2 of the RBCX procedure summary screens

Data	Description
Replaced: Depletion	Total volume of replacement fluid used during the depletion
Replaced: Exchange	Total volume of replacement fluid used during the exchange
Custom Prime	Total volume of fluid used for the custom prime
Saline Rinse	Total volume of saline used for the saline rinse

Starting a New Procedure

Unload the tubing set according to the instructions in the *Spectra Optia® Apheresis System Essentials Guide*, and then touch **New Procedure** on page 2 of the procedure summary. The system resets, so that you can select your next procedure.

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Red Blood Cell Exchange (RBCX) Procedure Guide

Spectra Optia®

Apheresis System

RBCX

TERUMOBCT
Unlocking the Potential of Blood

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Attachment 13.2

Spectra Optia Essentials Guide

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Spectra Optia®

Apheresis System

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ESSENTIALS

Essentials Guide

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Spectra Optia® Apheresis System

Essentials Guide

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and counterpart foreign patents:
Germany: 60035474.1, 60036906.4, 60041426.4, 60044623.9, 60044624.7, 60145279.8, 69618453.2, 69634860.8, 69636518.9, 69637310.6, 69637706.3, 69638219.9, 69638403.5, 69733198.9, 69739552.9, 69820404.2, 69836648.4, 69840459.9, 69842455.7, 602004027910.2, 602008010061.8
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Preface

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About This Guide

This guide is one of several guides that comprise the Spectra Optia Apheresis System Operator's Manual. It contains information and instructions on how to safely operate, transport, troubleshoot, and maintain the Spectra Optia system and the Seal Safe system. You should read and understand the information in this guide before operating the system. Use this guide in conjunction with the appropriate Spectra Optia Apheresis System procedure guide when performing a procedure on the system.

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Conventions Used in this Manual

This operator's manual uses certain conventions to help you identify the tasks that you must perform. This section describes these conventions.

Numbered Steps

All step-by-step instructions are numbered and the numbers appear in bold, as shown in the following example:

1 Carefully unpack the system from the shipping container.

Touch screen buttons

Many of the steps instruct you to touch a button on the screen. The text on the button appears in bold, as shown in the following example:

1 Touch **Confirm**.

Bullets

Bullets (•) are used to indicate items in a list.

Warnings, Cautions, and Notes

The following examples show how warnings, cautions, and notes appear in this document:

Warning: Warnings alert the operator of serious hazards, consequences, or conditions that are likely to result in a harmful reaction, trauma, or death to the patient or operator.

Caution: Cautions alert the operator to the possibility of a problem with the device associated with its use or misuse. This includes device malfunction, failure, and damage to the device or other property.

Note: Notes emphasize important details.

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Spectra Optia Apheresis System

Intended Use

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications and cell collections. Refer to the Spectra Optia Apheresis System procedure guides for information about using the system to perform specific procedures.

Contraindications for Use

There are no known contraindications for the use of the Spectra Optia system except those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

Warnings and Cautions for Use

Below is a complete list of warnings and cautions that apply to the use of the Spectra Optia system and the Seal Safe system. Although the information may also appear in other sections of this guide, the operator should read and understand the information in this list before using the system.

Some of the warnings or cautions may instruct you to contact Terumo BCT. Customers in the U.S. should contact Terumo BCT Customer Support. Customers outside the U.S. should contact their local Terumo BCT representative.

Warnings for Use

System warnings

1. DANGER: Do not use the Spectra Optia system in an explosive atmosphere.
2. To avoid possible patient injury or loss of life, use only operating procedures published by Terumo BCT.
3. Terumo BCT will not be responsible for patient safety if the procedures to operate the Spectra Optia system are other than those specified by Terumo BCT. Individuals performing the procedures must be appropriately trained and qualified.
4. Use only the filler and the tubing sets that Terumo BCT manufactures for the Spectra Optia system.
5. The manufacturer, assembler, installer, or importer regards itself as responsible for effects on the safety, reliability, and performance of the device, only if the device is employed in accordance with the instructions for use.

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6 The Spectra Optia system can interfere with EKG monitoring when a patient is simultaneously undergoing apheresis and EKG monitoring.

7 The Spectra Optia system alarms are inactive when the system is turned off.

Service warnings

8 To avoid possible patient injury or loss of life, use only maintenance procedures published by Terumo BCT.

9 Terumo BCT will not be responsible for patient safety if the procedures to maintain and calibrate the Spectra Optia system are other than those specified by Terumo BCT. Individuals performing the procedures must be appropriately trained and qualified.

10 Only a qualified service representative should perform equipment modifications. Any modifications must be approved in writing by Terumo BCT.

11 Turn off the system before cleaning to prevent possible electrical shock or damage to the equipment.

12 Unplug the system from the power supply before servicing.

13 Only a qualified service representative should service or repair the Spectra Optia system.

14 When cleaning and disinfecting equipment surfaces that might have been exposed to blood, take adequate precautions to prevent possible exposure to and transmission of infectious diseases.

Electrical warnings

15 All electrical installations must comply with all applicable local electrical codes and Terumo BCT's specifications.

16 To reduce the risk of electric shock do not use alternate power plugs or adapters that disconnect the green wire safety ground.

17 Non-medical electrical equipment connected to the Ethernet connection should not be located within the patient environment. The definition of "patient environment" can be found in the IEC standard 60601-1-1, 2.202.

18 Accessory equipment connected to the analog and digital interfaces must be certified according to applicable IEC standards (e.g., IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all system configurations shall comply with the system standard IEC 601-1-1. The installer of accessory equipment is responsible for the integrated medical system compliance with requirements of IEC 601-1-1. If you are in doubt, contact your Terumo BCT service representative.

Procedural warnings

19 Do not connect the patient before the system instructs you to do so.

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20 Rigorous attention should be paid to proper venipuncture site selection and decontamination.

21 It is advisable to obtain the patient's detailed drug history before each apheresis procedure. For those drugs potentially affected by apheresis procedures, the physician should either adjust the doses or give the medications immediately after the procedure.

22 Tubing sets manufactured by Terumo BCT contain DEHP. Results from selected studies of rodents exposed to DEHP (typically via an oral route) have shown potentially harmful effects to male reproductive organs during fetal development. Because of this, patient groups that include pregnant or nursing women and children are considered to be most at risk to potential harmful effects of exposure to DEHP. However, no studies performed to-date involving other mammals and humans exposed to intravenous DEHP have shown similar results. Regulatory bodies have noted that the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP. It is the responsibility of treating physicians to balance this risk for their patients.

23 The operator must verify the correct input of information relevant to the safety of each apheresis procedure.

24 When preparing to perform a procedure, ensure that the lines are connected to the correct fluids, and that fluid is flowing into the drip chambers:

- AC line (orange) to the anticoagulant container
- Saline line (green) to the normal saline (0.9%) container

25 Check that the tubing is correctly loaded in all pumps before starting a procedure. Visually inspect each pump to ensure that tubing does not protrude.

26 Before starting a procedure, inspect all lines, especially those in the centrifuge and on the front panel to ensure they are not obstructed. Tubing that is occluded or mechanically constrained can lead to malfunction or fluid imbalance. Inlet and return lines perform without difficulty as long as the interior diameter of the tubing is larger than the interior diameter of the patient's inlet and return access.

27 Only blood or blood products should be processed in the centrifuge.

28 If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

29 When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

30 Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

31 Monitor the return line for air. If you see air in the line, go to the operation status screen, touch **Remove Air From Return Line**, and follow the instructions on the screen.

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32 Before connecting the patient, ensure that the AC line contains anticoagulant at the inlet manifold.

33 The inlet and return pressure sensors are not intended to detect infiltrations of the vein. Monitor the patient for infiltrations.

34 Tubing sets may occasionally fail, which could result in the loss of blood, blood products, or the introduction of air into the tubing set. It is very important that the operator watch for leaks in the cassette, all tubing and welds, and in the channel while the set is in use. Operators should take adequate precautions in handling blood and blood products in accordance with their facility's standard operating procedures.

35 When handling extracorporeal blood circuits, take adequate precautions to prevent the possible exposure to and transmission of infectious diseases.

36 The following can cause fluid imbalance:

- Administration of replacement fluid that is not at room temperature during a procedure
- Use of improperly vented fluid containers
- Equipment malfunction
- Improperly clamped or closed lines, or improperly loaded valves
- Use of inadequately primed or clotted filters on the replace line of the Exchange Set
- Tubing that is incorrectly loaded in the pumps

37 The alarm system is inactive during a manual rinseback. If you must perform a manual rinseback, watch for air in the return line. If you see air, immediately discontinue the rinseback.

38 Do not apply excess pressure to the vent bag when pushing fluid from the reservoir to the patient during a manual rinseback or you could damage the Red Blood Cells that you are returning to the patient.

39 Do not continue to squeeze the vent bag after the fluid in the reservoir reaches the level of the reservoir filter during a manual rinseback. If you continue to squeeze the bag, you could deliver air to the patient.

40 Do not touch **Unload** to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

Solution and medicinal fluid warnings

41 When using biologically-derived replacement fluids, closely monitor the patient for reactions.

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42 Use only 0.9% sodium chloride solution for procedures performed on the Spectra Optia system. Using a solution with a different composition could cause hemolysis.

Seal Safe system warnings

43 Use only the sealer head and radio frequency (RF) cable provided by Terumo BCT with the Seal Safe system. The Seal Safe system does not function correctly with components from other tubing sealers.

44 Do not seal the tubing within 8 cm (3 in) of the needle, or you may cause a burn at the needle entry point.

45 Do not place your fingers within 2.5 cm (1 in) of the Seal Safe system's sealing jaw, or you may receive a radio frequency (RF) burn.

46 Do not release the lever of the sealer head until after the indication light goes out. Releasing the lever sooner could result in an inadequate seal.

47 Ensure that the sealer head and the tubing are free of moisture and debris before using the Seal Safe system.

48 Moisture on the surface of the tubing or the sealer head may cause an electrical arc to occur between the jaws when the power is applied, terminating the sealing process. If an arc occurs, carefully inspect the seal to ensure it is satisfactory.

49 Ensure that there is no tension on the tubing when operating the Seal Safe system. Stretching the hot tubing could cause a leak.

50 Do not submerge the Seal Safe system in liquid or you may receive an electric shock.

51 Disconnect the sealer head from the RF cable before cleaning to avoid receiving a serious radio frequency (RF) burn during the cleaning process.

52 The jaw on the sealer head contains an indentation where the spring rests. If you do not properly seat the spring in the indentation after cleaning, you may damage the spring, which could cause inadequate tubing seals.

53 Do not open the sealer head to service the device or you may receive an electric shock. Contact a qualified service representative to service the device.

Cautions for Use

System cautions

1 Use of the Spectra Optia system is restricted to prescription only.

2 Each operator should be thoroughly familiar with the Spectra Optia system's operating instructions before using the system. All procedures should be performed by qualified medical personnel under the supervision of a physician.

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3 The Spectra Optia system and the Seal Safe system comply with all relevant international standards concerning electromagnetic emissions and compatibility. Before undergoing apheresis, patients with active implantable medical devices should review the implant manufacturer's instructions for any cautions or contraindications concerning the use of and/or proximity to devices that emit electromagnetic energy. Examples of active implantable devices include cardiac pacemakers and cardioverter defibrillators, cochlear implants, vagus nerve stimulators, and devices that stimulate the peripheral or central nervous systems. This caution also extends to other devices that may connected to the patient such as ECG equipment and infusion systems. Care should be taken to prevent the Seal Safe system from touching the patient or any cables of the devices that may be connected to the patient.

4 Do not use the Spectra Optia system under any of the following conditions:

- Power cords, plugs, or receptacles are damaged or worn.
- Switches are loose.
- System has received a physical shock, or liquid has spilled on the electronics housed under the cover.
- Anyone has received an electrical shock while using the system.
- System appears to be overheating.

5 Keep hair, fingers, clothing, and other articles away from pumps and valves to avoid entanglement.

6 Do not put open containers containing fluid on the device. Fluid spills can contribute to electrical and mechanical hazards.

7 To avoid damage to the Spectra Optia system, do not operate the centrifuge without a filler installed or before loading the channel.

8 Before installing a filler or loading a tubing set, inspect the filler and visible interior of the centrifuge chamber for fluid spills or structural damage. Ensure the metal band around the perimeter of the filler is centered and secure.

9 To avoid damage to the centrifuge and the filler, do not operate the centrifuge if the filler latch is not lowered and locked in place. Ensure that the filler cannot be pulled off the gear train without unlocking and raising the filler latch.

10 To avoid personal injury or damage to the system, use proper lifting techniques when lifting the Spectra Optia system.

11 Ensure that the wheel pedal is pressed to the right (locked) position during procedures, so that the Spectra Optia system does not move.

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12 In the event of a prolonged power interruption, the use of an uninterruptible power supply (UPS) may allow the operator to discontinue the procedure and perform rinseback. However, a UPS does not ensure that the operator can complete the procedure as intended.

Service cautions

13 Clean the Spectra Optia system using a mild cleaning solution, or a mild detergent. Industry standard practice defines mild detergent as a solution or detergent that is safe on skin and on washable surfaces, such as hand dishwashing liquid. Use of a solution that is not compatible with the materials on the system may damage the material or operating characteristics of the system.

14 Disinfect the Spectra Optia system using a 0.25% sodium hypochlorite (bleach) solution. Use of a stronger bleach solution may damage or discolor the system.

15 To avoid scratching the Spectra Optia system touch screen or the glass covers on the lights inside the centrifuge, do not clean the screen or covers with an abrasive brush or scrub material.

16 Do not use alcohol or alcohol-based products to clean the touch screen to avoid damaging the screen's surface.

17 Do not spray or douse the Red Blood Cell (RBC) detector with liquid to clean it. Using an excessive amount of liquid can damage the detector. If you must spray the front panel, cover the RBC detector beforehand.

18 Terumo BCT has validated the methods described in this manual for cleaning and decontaminating the Spectra Optia system. Before using an alternative method, verify that it will not damage the system.

19 Do not lubricate pumps or pump rotors for any reason.

Procedural cautions

20 The Spectra Optia system has many safety features. However, a patient reaction can occur rapidly. Therefore, it is imperative that the operator monitor the patient and the system throughout the procedure.

21 The physiological condition of patients may affect the outcomes of procedures performed on the Spectra Optia system.

22 Patients with impaired or abnormal citrate metabolism (for example, if the patient has liver or renal disease) may present an increased risk of citrate sensitivity. Attending physicians should assess the appropriateness of such patients for apheresis procedures and prescribe how they should be monitored during procedures.

23 Use aseptic technique throughout all procedures to ensure patient safety and product quality.

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24 Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit. The attending physician is responsible for prescribing the anticoagulant used, however, and all personnel involved in performing apheresis procedures should read the anticoagulant manufacturer's product insert before use.

25 The higher the inlet:AC ratio used during the procedure, the greater the risk is for aggregates and clumps to form in the tubing set.

26 For patient comfort and optimal system operation, ensure that the fluids used during the procedure are at room temperature before connecting them to the tubing set.

27 Do not connect the fluids to the tubing set before the system instructs you to do so.

28 To avoid a failed test of the tubing set, do not raise and lower the cassette after there is fluid in the set.

29 Follow local transfusion practices when performing a custom prime.

30 If you leave the roller clamp on the saline line completely open when the patient is connected, you will quickly infuse a large volume of saline to the patient.

31 All used disposable materials should be considered hazardous, and should be handled and disposed of at the end of the procedure in accordance with all applicable regulations.

General tubing set cautions

32 **Not for Reuse**: Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.

33 The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:

- Severe kinks in the tubing are apparent.
- Tubing set appears to be incorrectly assembled.
- Tubing set is damaged.
- Any clamps are closed on the lines.

34 You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.

35 Do not stretch the tubing when folding the channel to install it in the centrifuge to avoid damaging the tubing set.

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36 Use only your fingers to load the channel into the filler. To avoid puncturing the channel, never use a sharp object.

37 Do not seal the inlet line of the four-lumen tubing. Sealing the line could cause the tubing set to fail when you raise the cassette to unload the set.

38 Ensure all luer connections are secure.

Exchange Set cautions

39 Do not use the Exchange Set if the end caps are not in place.

40 Leave the cap on the unused luer (on the remove bag) to prevent fluid leakage. Ensure the cap fits tightly.

Collection Set cautions

41 The Collection Set is no longer considered functionally closed if any of the following conditions are true:

- Inlet needle is not connected, or the end caps on the lines of the tubing set are missing when you open the package.
- First attempt to insert the inlet needle fails (unless you attach a new needle using a connection device that maintains the sterility of the tubing set).
- Inlet needle is disconnected during the procedure.
- If using the diversion bag to collect a blood sample, the sample is taken before the line to the bag is sealed.
- Any product bag or the diversion bag is disconnected before the line to the bag is sealed.
- Product sample is removed from the sample bulb before you permanently seal the line.
- Sterile barrier filters are damaged.
- Integrity of the tubing set is compromised for any reason.

42 To correctly lock the needle protector over the inlet needle, you must hold it in place while you pull the tubing to remove the needle. It will not lock if you use the wings of the needle or the body of the needle protector to remove the needle. After use, visually confirm that the needle protector is locked over the needle and that the wings are secured behind the locked prongs.

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Seal Safe system cautions

43 The Spectra Optia system and the Seal Safe system comply with all relevant international standards concerning electromagnetic emissions and compatibility. Before undergoing apheresis, patients with active implantable medical devices should review the implant manufacturer's instructions for any cautions or contraindications concerning the use of and/or proximity to devices that emit electromagnetic energy. Examples of active implantable devices include cardiac pacemakers and cardioverter defibrillators, cochlear implants, vagus nerve stimulators, and devices that stimulate the peripheral or central nervous systems. This caution also extends to other devices that may connected to the patient such as ECG equipment and infusion systems. Care should be taken to prevent the Seal Safe system from touching the patient or any cables of the devices that may be connected to the patient.

44 Use the Seal Safe system only on tubing distributed by Terumo BCT. The Seal Safe system may not perform as expected on other tubing.

45 To avoid possible damage to the Seal Safe system, always disconnect the sealer head and the RF cable before transporting the Spectra Optia system.

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Service Information

Terumo BCT and/or its subsidiaries will not be responsible for the safety, reliability, or performance of this equipment unless:

- Operational procedures, calibration, and repairs are carried out by appropriately qualified persons.
- All equipment modifications are authorized in writing by Terumo BCT and performed by appropriately qualified persons.
- The electrical installation of the relevant room complies with all applicable local electrical codes and IEC requirements.
- The equipment is used in accordance with the published instructions for use.

Detailed service information for this equipment, including schematic diagrams and recommended service procedures, is available from your Terumo BCT representative.

Special Use of Additional Equipment and Devices During Apheresis Procedures

You may require one or more of the following items to complete an apheresis procedure using the Spectra Optia system:

- Blood/fluid warmer
- Solutions and medicinal fluids

For instructions on safely using additional items with the Spectra Optia system, refer to the guidelines provided by the equipment or device manufacturer.

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Solutions and Medicinal Fluids Administered During Apheresis Procedures

This section includes descriptions of solutions and medicinal fluids that may be used during apheresis procedures on the Spectra Optia system.

Saline Solution

Use sterile 0.9% sodium chloride solution to prime the tubing set and to perform the procedure.

Anticoagulant

ACD-A

Each 100 mL of ACD-A contains 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous.

Citrate toxicity

ACD-A can cause citrate toxicity in certain patients. Mild forms of this condition are generally recognized by peripheral paresthesia, tingling sensations in the extremities, and/or restlessness. Severe forms of this condition can result in significant cardiac dysfunction. Terumo BCT recommends that you frequently assess the condition of the patient throughout the apheresis procedure.

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Adverse Effects of Apheresis Procedures

Be aware of possible patient reactions to apheresis procedures, and be prepared to take appropriate action should any reactions occur. Some previously reported reactions are:

- Anxiety
- Headache
- Light-headedness
- Digit and/or facial paresthesia
- Fever
- Chills
- Hematoma
- Hyperventilation
- Nausea and vomiting
- Syncope (fainting)
- Urticaria
- Hypotension
- Allergic reactions

Reactions to Blood Products Used for a Custom Prime

Reactions to transfused blood products can include fever, circulatory overload, shock, allergic reactions, alloimmunization, and Graft-vs.-Host disease, as well as transmission of infectious diseases and bacteria. (Sources: *Circular of Information for the Use of Human Blood and Blood Components*, AABB, et al, ed., April, 2006; *Guide to the preparation, use and quality assurance of blood components*, 10th Edition, Council of Europe Publishing.)

Disposal of Infectious and Non-Infectious Waste

Follow your local regulations for disposing of material that may be contaminated with biohazardous products.

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2

Introduction

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Spectra Optia System Description

The Spectra Optia Apheresis System is a transportable, automatic blood component separator that uses centrifugation and optical detection (automated interface management system or AIM system) to perform therapeutic apheresis procedures.

The Spectra Optia system's touch screen interface enables the operator to communicate with the system. The operator follows the instructions on the screen to enter patient and procedure data, load and prime the tubing set, and perform and troubleshoot procedures. The system displays detailed information about the procedure, so that the operator can adjust the run values to achieve a specific outcome, or troubleshoot a condition. After the procedure is complete, the system provides a report of procedure data for the patient record.

Spectra Optia System Components

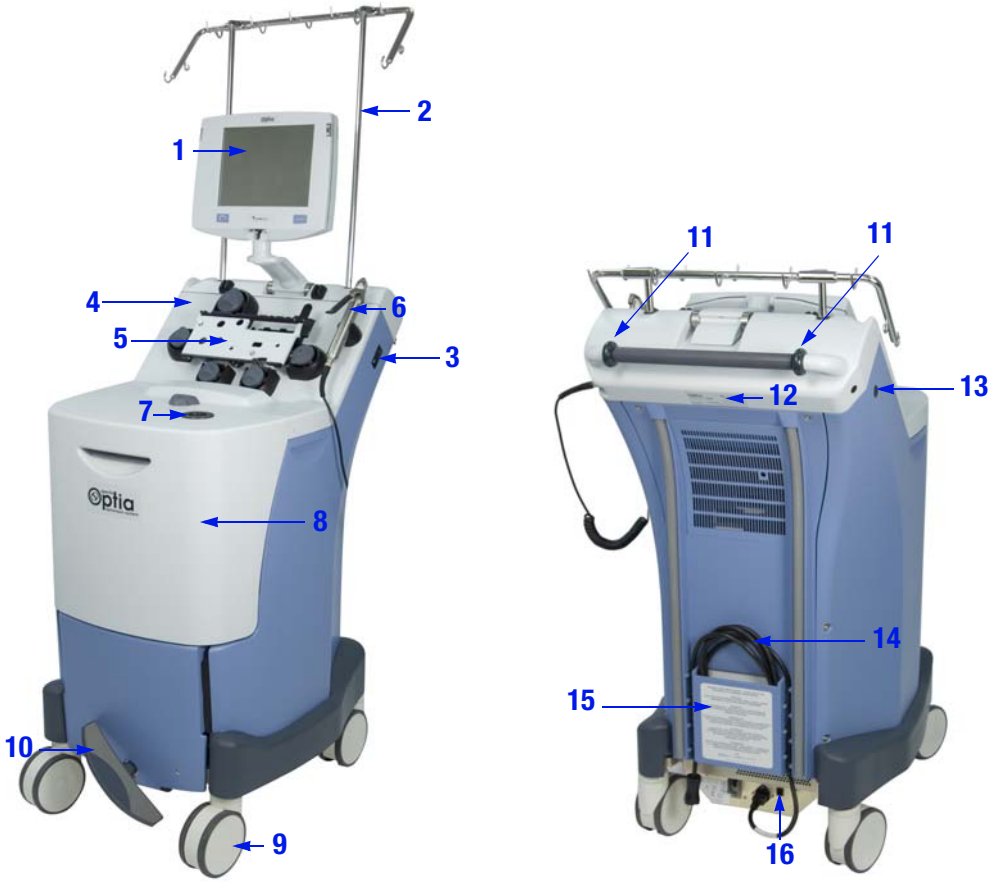

Figure 2-1: Spectra Optia Apheresis System front and back views

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Table 2-1: Spectra Optia system components

	Component	Function
1	Monitor with touch screen	Allows you to communicate with the system.
2	Dual IV pole	Has hooks for hanging bags and containers. You can adjust the height of the pole for transporting the device, or to hang and remove bags.
3	Power switch	Allows you to turn power to the system on and off.
4	Front panel	Holds the pumps, valves, sensors, and detectors.
5	Cassette tray	Holds the tubing set cassette in place.
6	Seal Safe system	Seals the lines of the tubing set.
7	View port	Allows you to look through the centrifuge door to see the interface in the channel.
8	Centrifuge door	Allows access to the centrifuge chamber.
9	Wheels	Used to transport the system.
10	Wheel pedal	Allows you to adjust the direction of the wheels for moving the system, or lock the wheels in place so that the system does not roll.
11	Handle wheels	Used to facilitate transport of the system in a horizontal position.
12	System serial number	Unique number used to identify the system.
13	IV pole release button	Allows you to lower the IV pole by pressing the button.
14	Power cord	Connects the system to a power source.
15	Power cord holder	Secures the power cord during transport.
16	Ethernet connection	Allows you to connect the system to a printer or a computer to print a procedure report.
17	Accessory bracket (not shown)	Can be used to hold an additional device used during an apheresis procedure, such as a blood warmer or an infusion pump.

Front Panel

The front panel of the Spectra Optia system holds the pumps, sensors, and valves that are used to perform an apheresis procedure. The locations of the components are shown in Figure 2-2,

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and the functions are described in Tables 2-2 through 2-4.

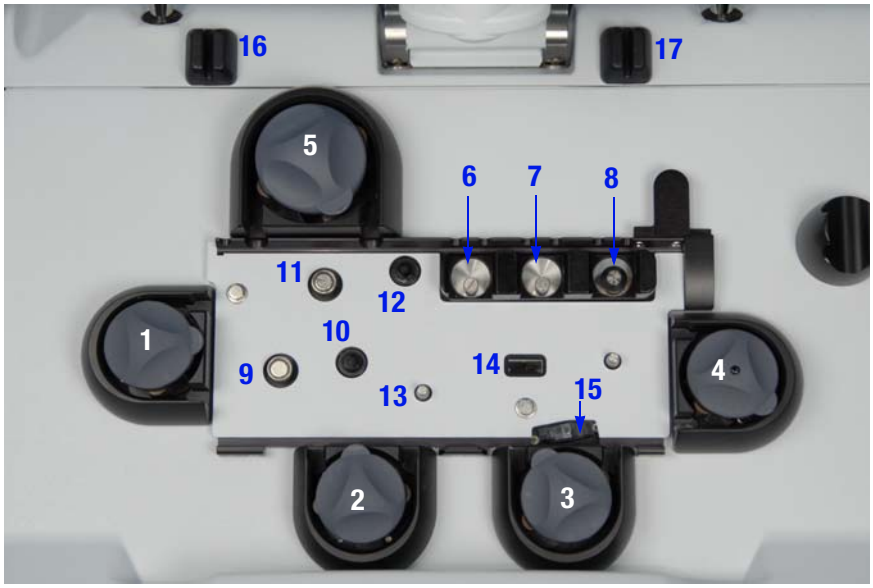

Figure 2-2: Front panel components

Pumps

Table 2-2: Functions of the Spectra Optia system pumps

	Pump	Function
1	Anticoagulant (AC) pump	Pumps anticoagulant from the AC container to the inlet line.
2	Inlet pump	Pumps anticoagulated blood from the patient to the channel.
3	Plasma pump	Pumps Plasma out of the channel.
4	Replace pump (Exchange) Collect pump (Collection) (black dot on the pump rotor)	Exchange procedures: Pumps replacement fluid out of the fluid container. Collection procedures: Pumps the collected component out of the channel or chamber.
5	Return pump	Pumps the contents of the reservoir to the patient.

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Valves

Table 2-3: Functions of the Spectra Optia system valves

	Valve	Function
6	Red Blood Cell (RBC) valve	Directs the flow of Red Blood Cells from the channel.
7	Plasma valve	Directs the flow of Plasma from the channel.
8	Remove valve (Exchange) Collect valve (Collection)	Directs the flow of the separated blood components from the channel.

Sensors and detectors

Table 2-4: Functions of the Spectra Optia system sensors and detectors

	Sensor/Detector	Function
9	Inlet pressure sensor	Monitors negative pressure in the inlet line to ensure that adequate inlet pressure is maintained.
10	Low-level reservoir sensor	Monitors the volume of fluid in the reservoir, and ensures that air does not enter the return line.
11	Return pressure sensor	Monitors positive pressure in the return line to ensure that the correct level of return pressure is not exceeded.
12	High-level reservoir sensor	Monitors the volume of fluid in the reservoir to help control the volume of fluid in the system.
13	Centrifuge pressure sensor	Monitors pressure in the channel and lines in the centrifuge to ensure that the correct level of pressure is not exceeded.
14	Bar code reader	Reads the tubing set identification number on the cassette to ensure that the correct tubing set is loaded for the procedure selected.
15	Red Blood Cell (RBC) detector	Exchange procedures: Detects Red Blood Cells in the Plasma line. Collection procedures: Detects Red Blood Cells in the collect line.
16	Anticoagulant (AC) fluid detector	Detects fluid in the AC line. Signals the system if the line contains air instead of fluid.
17	Replacement fluid detector	Detects fluid in the replace line during exchange procedures. Signals the system if the line contains air instead of fluid.

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Centrifuge Chamber

The Spectra Optia system centrifuge spins to create a centrifugal force that separates the blood into cellular components. The centrifuge chamber houses the centrifuge and the system components, as shown in Figure 2-3 and described in Table 2-3.

Figure 2-3: Centrifuge chamber components

Table 2-5: Functions of the Spectra Optia system centrifuge chamber components

	Component	Function
1	Upper collar holder	Secures the upper collar at the entrance to the centrifuge chamber.
2	Fluid leak detector	Detects moisture in the centrifuge chamber.
3	Upper strobe (lower strobe is not shown)	Illuminates the interface to allow you to view the interface through the view port.
4	Loading port	Allows access to the filler from the center of the centrifuge.
5	Centrifuge arm	Holds the upper and lower bearing holders.
6	Upper bearing holder	Secures the upper bearing to the tip of the centrifuge arm.
7	Lower bearing holder	Secures the lower bearing at the entrance to the loading port.
8	Filler	Secures the tubing set channel, the connector, and the lines that are attached to the connector to the centrifuge.

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Table 2-5: Functions of the Spectra Optia system centrifuge chamber components (continued)

	Component	Function
9	Gear shroud	Covers the centrifuge gear train.
10	Lights (Not shown. One light is located on the top of the chamber and the second is located on the bottom behind the gear shroud.)	Component of the AIM system. Illuminate the interface to allow the AIM system to view the interface.

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Filler

The filler secures the tubing set channel, the connector, and the lines that are attached to the connector to the centrifuge.The locations of the filler components are shown in Figure 2-4, and the functions are described in Table 2-6.

Figure 2-4: Filler components

Table 2-6: Functions of the Spectra Optia system filler components

	Component	Function
1	Aperture plate (arrow points toward the plate)	Plastic component attached to the underside of the filler directly beneath the opening for the connector. The aperture plate ensures uniform lighting to the appropriate areas of the connector, and helps the AIM system control the concentration of cells that flow through the collect port during a collection procedure.
2	Chamber bracket	Secures the chamber of the Collection Set.
3	Groove	Secures the channel and the connector in the filler.
4	Centrifuge collar holder	Secures the lower collar of the tubing set at the opening to the centrifuge loading port.
5	Filler latch	Locks the filler onto the centrifuge.
6	Optical reference	Provides a reference point for the AIM system to use to determine the position of the interface during a procedure.

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Operating Modes

The Spectra Optia system has two modes of operation, Automatic and Semi-Automatic. This section describes the modes.

Automatic Mode

During Automatic mode, the system uses the settings selected for the configuration parameters and the procedure data entered to set and control the pump flow rates, centrifuge speed, packing factor, run targets, and to establish the interface position. The system then uses feedback it receives from the AIM system to control the interface position, so it can remove or collect the desired blood component, and return the fluid remaining in the channel to the patient.

Semi-Automatic Mode

During Semi-Automatic mode, the system does not control the position of the interface. There are two reasons to enter Semi-Automatic mode: You may be required to enter Semi-Automatic mode to resume the procedure if certain alarms occur, or you may choose to enter Semi-Automatic mode under certain procedure conditions. Refer to the Spectra Optia Apheresis System procedure guides for procedure-specific instructions on using Semi-Automatic mode.

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Procedure States

Table 2-7 describes the Spectra Optia system's procedure states. Both Automatic and Semi-Automatic mode include these states.

Table 2-7: Procedure states

State	Description
Load	Operator selects the procedure and loads the appropriate tubing set.
Tubing set test	System verifies that the correct tubing set is properly loaded, and confirms the function of the pumps, valves, and sensors.
Prime	System primes the tubing set to remove air from the set, to perform volumetric tests, and to balance the pumps prior to the start of the run.
Run	Patient is connected and the system performs apheresis, according to the selected procedure.
Rinseback	System returns the blood remaining in the tubing set to the patient after the run is complete to reduce the patient's RBC loss. The operator may choose to perform or skip rinseback.
Disconnect test	System verifies that the lines to the patient are clamped.
Unload	System raises the cassette and unloads the tubing from the pumps.
Procedure summary	System displays the final procedure values.
Next procedure	System prepares for the next procedure.

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Caution Status

Caution status alerts you that the system is operating outside of certain established limits. When the system is operating in Caution status, a yellow border appears on the bottom of the screen. The yellow border disappears if the system operation changes and Caution status no longer applies. To view why the system is operating in Caution status, touch the **Operation Status** tab. The reason is explained in yellow text on the screen.

The system automatically enters Caution status if the AC infusion rate entered is greater than 1.2 mL/min/L of TBV. Refer to the Spectra Optia Apheresis System procedure guides for additional procedure-specific conditions when Caution status applies.

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Spectra Optia System Touch Screen

Navigating the Screen

The Spectra Optia system's touch screen allows you to perform, adjust, and monitor procedures. The screen is divided into several sections, as shown in Figure 2-5 and described in Table 2-8.

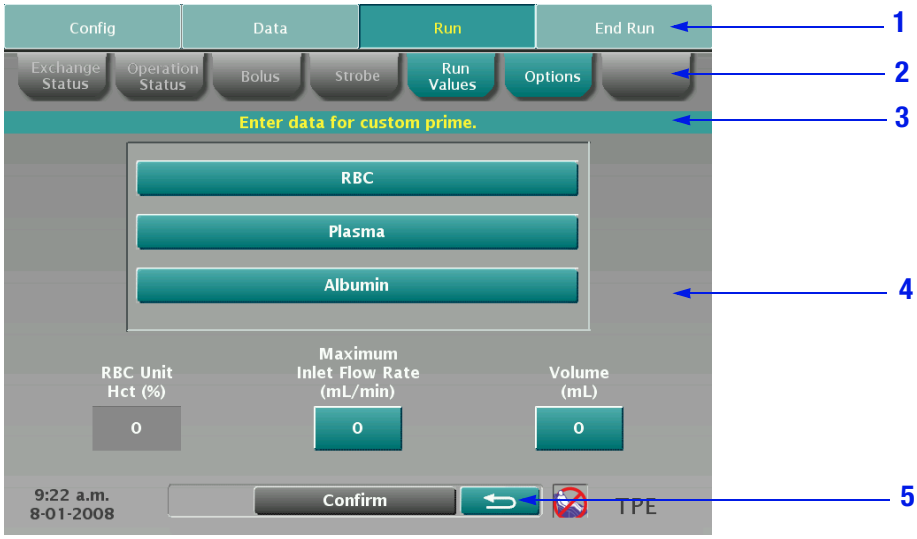

Figure 2-5: Example of a Spectra Optia system screen

Table 2-8: Sections of the Spectra Optia system screen

	Section	Description
1	Menu bar	Contains menu buttons that you touch to show or hide menu tabs.
2	Menu tabs	Appear according to the menu button that you touch. Tabs provide access to screens that allow you to view information or modify the procedure.
3	Message bar	Displays instructions to enter data or information about the status of the procedure.
4	Activity area	Displays tasks to complete and buttons that allow you to: • Navigate to another screen. • Change the operating mode. • Change values or information about the procedure.
5	Action bar	Contains buttons that you touch to perform the action stated on the button or to navigate to a different screen.

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Screen Colors

The Spectra Optia system uses a color scheme to indicate the different procedure states, allowing you to quickly determine the progress of the procedure. Table 2-9 describes the color scheme that corresponds to each procedure state.

Table 2-9: Color schemes for procedure states and conditions

Procedure State	Color
Load, prepare procedure, tubing set test, prime (patient is not connected)	
Run, rinseback, disconnect test (patient is connected)	
Unload, procedure summary, next procedure (patient is disconnected)	

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Screen Buttons

The screen displays active and inactive buttons, as shown in the following examples:

- Active button:

  Active buttons are colored according to the procedure state and appear raised. Touch an active button to enter, change, or save data, or to proceed to the next activity or action.

- Inactive button:

  Inactive buttons are gray. They indicate that the action or the information is not available.

Graphics of buttons and icons

The buttons and icons described in Table 2-10 appear on the monitor or the screens, and either allow you to operate and adjust the Spectra Optia system during an apheresis procedure, or communicate important information. Refer to the Spectra Optia Apheresis System procedure guides for buttons and icons that appear only during specific procedures.

Table **2-10:** Spectra Optia system buttons and icons

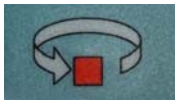
Graphic	Description	Location	Function
	Go back button	• Bottom right side of screens • Top left side of the report summary screen and the report detail screen	Returns you to a previous screen or to the main run screen. The button is available only when it is safe to return to a previous screen. On some screens you must confirm any data you change before you touch the go back button or the data will not be saved.
	Mute button	Bottom left side of screens during an alarm condition	Allows you to mute the sound during an alarm condition. The sound is restored if another alarm occurs.
	Stop button	Bottom left corner of the monitor	Stops the centrifuge and the pumps.

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Table **2-10:** Spectra Optia system buttons and icons (continued)

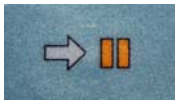
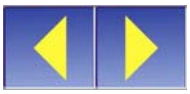
Graphic	Description	Location	Function
	Pause button	Bottom right corner of the monitor	Pauses the pumps.
	Active alarm button	Bottom left side of the screen during an alarm condition	Indicates an active alarm. Takes you to an active alarm screen, or to a list of active alarms if more than one is active.
	Clock button	• Run time graph on the main run screen • Exchange procedures: Run time graph on the exchange status screen	Allows you to view clock time or elapsed time for the run.
	Up/down scroll buttons	• Active alarm screens • Alarm history screen • Procedure selection screen	Allows you to view additional information on the screen.
	Left/right arrow buttons	Strobe screen	• Allows you to adjust the timing of the strobe. • Allows you to view different areas of the channel.
	Left/right scroll buttons	• Alarm action screens • Report summary screen • Report detail screen	• Allows you to scroll through alarm action screens, so you do not have to return to the active alarm screen to view additional causes and actions. • Allows you to scroll through pages of the report summary screen and the report detail screen.
	Check mark icon	• Prepare procedure screen • Patient data screen	Appears on buttons. Indicates the required task is complete or the selection is confirmed.

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Table **2-10:** Spectra Optia system buttons and icons (continued)

Graphic	Description	Location	Function
	Do not connect patient icon	Bottom right side of screens before the patient is connected	Safety feature that reminds you that the patient should not be connected during the current operating state.
	Operator override icon	TBV (total blood volume) button on the patient data screen	Indicates the operator entered the patient's TBV instead of using the volume the system calculated.
	Semi-Automatic mode icon	Bottom right side of run screens	Indicates the system is operating in Semi-Automatic mode.

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Installing and Transporting the Spectra Optia System

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Installing the Spectra Optia System

Installation information is included in the shipping container of each Spectra Optia system. An authorized service representative uses this information to install the system in your facility. The service representative also tests the system to confirm it is functioning properly before you begin using it.

Setting Up the Spectra Optia System

Perform the following steps to set up the Spectra Optia system:

1. Carefully unpack the system from the shipping container.
2. Put the system in the desired location and press the wheel pedal to the right side to lock the system in place.
3. Establish a safety boundary of at least 30 centimeters (11.8 inches) around the perimeter of the system from all points within which hazardous material is not permitted. When the centrifuge is spinning, limit access inside the boundary to necessary individuals.
4. Raise the monitor until it is fully upright.
5. Raise the IV pole.
6. Plug in the system to a properly installed, three-wire, grounded electrical receptacle that is protected by an approved branch circuit overcurrent protection/disconnection device. The branch circuit protection/disconnection device must be located away from but close enough to the system so that the system can be easily disconnected from the main power supply if the centrifuge malfunctions.

Turning the Spectra Optia System On and Off

1. Confirm that the proper power cord is attached to the system and plugged into an appropriate electrical receptacle.
2. Press the power switch on the upper-right side of the system to the ON position. The system performs a series of self-diagnostic tests to validate the functionality of the hardware and software before you begin the procedure. Once the tests are complete, the buttons on the screen are enabled and you may begin the procedure.
3. To turn off the system, press the power switch to the OFF position.

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Transporting the Spectra Optia System

Preparing the Spectra Optia System for Transport

1. Unplug the Spectra Optia system and secure the power cord in the power cord holder.
2. Press the IV pole release button located on the left side of the front panel and lower the IV pole.
3. Lower the monitor and lay it over the front panel (Figure 3-1).

Figure 3-1: Lowering the monitor over the front panel

4. Remove the sealer head of the Seal Safe system from the holder and detach the cable from the side of the Spectra Optia system. Separately transport the sealer head and cable to avoid damage to the connection.

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5 Press the wheel pedal to the appropriate position:

- To lock the front wheels in a forward position for moving in corridors, press the wheel pedal to the left.
- To allow free movement of all wheels, press the wheel pedal to the horizontal position.
- To lock the front wheels in position when performing a procedure, press the wheel pedal to the right (Figure 3-2).

Figure 3-2: Front wheels in the locked position

Transporting the System in a Vehicle

To safely transport the system in a vehicle, perform the following steps:

1 Perform steps 1 through 4 of "Preparing the Spectra Optia System for Transport" on page 35.

2 To transport the system in a horizontal position, perform steps a. and b. below. To transport the system in a vertical position, go to step 3.

a. Tip the system backward so that the front wheels are off the ground.

b. Lay the system so that it rests on the rear wheels and the two small wheels on the handle of the system.

3 Carefully load the system into the vehicle. Do not place any weight or objects on the monitor while it is in the transport position.

4 Properly secure the system in the vehicle, so that it remains stable during transport. If you are transporting the system in a vertical position, ensure that you lock the wheels.

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Storing the Spectra Optia System

Cover the Spectra Optia system and store it in a clean environment, according to the specifications stated in Table 9-2 on page 90.

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Configuration and Procedure Data Management

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Configuring the Spectra Optia System

The Spectra Optia system allows you to configure procedure-independent and procedure-specific operating parameters to meet your facility's requirements. Configuration settings for the procedure-independent parameters apply to all procedures. Configuration settings for procedure-specific parameters apply to only the specified procedure type. Several parameters have a default setting. The system uses the default setting unless you enter a different setting. You must touch **Confirm** after you finish configuring the parameters in order for the settings to take effect.

To configure the parameters, perform the following steps:

1. Touch the **Config** menu button. The configuration tabs appear.
2. Touch the tab for the parameters that you want to configure. The corresponding configuration screen appears.
3. Touch the button for the parameter that you want to configure:
   - For parameters with only two settings, toggle between the settings until the setting that you prefer appears on the button.
   - For parameters with more than two settings, a list appears to enable you to select a setting.
   - For parameters that require a numeric setting, a data entry pad appears to enable you to enter a number. The range of acceptable values appears on the data entry pad.
4. Repeat step 3 until you finish configuring the parameters.
5. Touch **Confirm**.

Configuring Procedure-Independent Operating Parameters

You may configure most procedure-independent operating parameters after you turn on the system and before you connect the patient. You may not change the language setting after you select a procedure, however. Tables 4-1 and 4-2 show the configuration parameters and setting options for the procedure-independent parameters.

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System

Table 4-1: System configuration parameters and setting options

Parameter	Description	Setting Options
Language	Language that appears on the screen. You must select a language before you can select a procedure.	• English • Additional languages are available based on the country in which the system is used.
Height units	Unit of measure for the patient's height	• ft in (feet, inches) • cm (centimeters)
Weight units	Unit of measure for the patient's weight	• lb (pounds) • kg (kilograms)
Alarm volume	Volume of the alarm tone	• Low • High
Software	Software version and verification value for each type of procedure. This information is used to confirm that the system software version and verification value for a particular procedure type have not changed after software for a new procedure type was installed.	Not configurable
Decimal	Punctuation used to represent a decimal point	• 0,00 (comma) • 0.00 (point)
Time format	Format used to display the time	• hh:mm (24-hour) • hh:mm (12-hour, am/pm)
Current time	Current time	• hh:mm (24-hour) • hh:mm (12-hour, am/pm)
Date format	Format used to display the date	• mm-dd-yyyy • dd-mm-yyyy
Current date	Current date	• mm-dd-yyyy • dd-mm-yyyy

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Report

Table 4-2: Report configuration parameters and setting options

Parameter	Description	Setting Options
Device	Device that is used to deliver a copy of the report. If you select “Printer”, you must also select a paper size.	• No Device • Printer • Computer
Connection	Test used to verify that a device for printing a report is connected to the system. If the system can verify the connection, “Passed” appears on the button. If the system cannot verify the connection, “Failed” appears.	Test
Paper	Size of paper that is used to print the report, if “Printer” is the device selected.	• Letter • A4
Report	Type of procedure report that you want to view or print.	• Summary (single page report including system serial number, date of procedure, patient information, fluid balance, and initial and final run values) • Detail (Summary report plus additional procedure details, which are reported according to the report update interval you entered.)
IP address	IP address for the device that is used to print the report.	Device-specific. The format for the address is XXX.XX.XXX.XXX. The first five digits must be 172.21 to match the system’s address.
Report update interval (min)	Interval at which procedure information appears on the report.	10 to 60
Port	Port number for the device that is used to print the report.	Format for the number is XXXX. The default number is 9100. It is recommended that you use the default.

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Configuring Procedure-Specific Operating Parameters

You may configure procedure-specific operating parameters before you enter and confirm the patient data. See the appropriate Spectra Optia Apheresis System procedure guide for instructions on configuring procedure-specific operating parameters

Entering Data During the Procedure

The system requires that you enter specific data, such as patient data, during the procedure. You may also change numerical values for operating parameters as you monitor the run. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad also displays the established range for the parameter, or the calculated range if the range adjusts based on related data. See the appropriate Spectra Optia Apheresis System procedure guide for data entry ranges.

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Printing Procedure Data Reports

The Spectra Optia system stores procedure data reports for up to one hundred procedures. Perform the steps below to connect a printer or a computer to the Spectra Optia system, and print a copy of a report.

Connecting a Printer to the Spectra Optia System

Ensure the printer meets the following requirements before connecting it to the system:

- Printer must be network compatible. The system cannot communicate with Universal Serial Bus (USB) or parallel printers.
- Printer must be compatible with PostScript® 3™ page description language. The system does not communicate properly with printers that are only compatible with earlier versions of the language.
- Printer must have a configurable Internet Protocol (IP) address.
- Printer must be able to use port number 9100 for Local Area Network (LAN) printing.
- Ethernet cable used to connect the printer to the system must be a cross-over cable.

Note: If you are connecting the system to the printer via a network device, such as a router or a switch, use a standard Ethernet cable.

Perform the following steps to connect your Spectra Optia system to a printer:

1. Connect one end of the cross-over cable to the printer, and the other end of the cable to the Ethernet port on the Spectra Optia system. The Ethernet port is located on the bottom right side of the back of the system next to the connection for the power cord.
2. Configure the parameters and options on the report configuration screen to use a printer to print a copy of the report (see Table 4-2 on page 42).
3. Touch **Test** on the connection button to verify the connection between the system and the printer.

For additional information about connecting a printer to the Spectra Optia system, visit www.terumobct.com or contact your local Terumo BCT service representative.

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Connecting a Computer to the System

Ensure the computer meets the following requirements before connecting it to the system:

- Computer must have the following applications installed:
  - File Transfer Protocol (FTP) server software
  - Software used to create Portable Document Format (PDF) files from PostScript files
- Ethernet cable used to connect the computer to the system must be a cross-over cable.

Note: If you are connecting the system to the printer via a network device, such as a router or a switch, use a standard Ethernet cable.

For additional information about connecting a computer to the Spectra Optia system, visit www.terumobct.com or contact your local Terumo BCT service representative.

Printing a Report

Perform the following steps to deliver the report to either a printer or a computer for printing:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Report** tab. The screen appears with a list of reports in order of the most recent procedure to the least recent procedure. The reports are identified by the procedure date, start time, procedure type, and the patient's TBV. To view additional reports, touch the scroll bar.

   Note: The button on the screen for the report for a procedure that was just completed is labeled **Current**.

3. Touch the button that corresponds to the report you want to print. The report appears on the screen.
4. Touch the button at the top left side of the report to deliver a copy of the report to the device specified on the report configuration screen:
   - If you selected a printer, **Print** appears on the button.
   - If you selected a computer, **Print to File** appears on the button.
   - If you did not select a device and only intend to view the report, **No Device** appears on the button.

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Selecting Procedure Options

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Selecting Procedure Options

This chapter describes the Spectra Optia system's procedure options. Procedure options are optional steps that you may choose to perform during a procedure. You can select the options after you select a procedure type. The options are summarized in Table 5-1.

Table 5-1: Procedure options

Procedure Option	Description
Rinseback	Allows you to specify if the system should perform or skip rinseback at the end of the run. If you perform a custom prime, the system will automatically skip rinseback unless you specify otherwise.
Custom prime	Allows you to fill the tubing set with specified fluid after you prime the set with saline and before you connect the patient. When treating a patient with a low RBC volume or a low blood volume, such as a pediatric patient, this option allows you to perform a custom prime to maintain isovolemia.
Saline rinse	Allows you to rinse the tubing set with saline solution when you are concerned about hypersensitivity reactions associated with residual ethylene oxide in the tubing set, which is a by-product of sterilization. This option is available to select before you connect the patient.
Blood warmer	Allows you to indicate the use of a blood warmer during the procedure, without changing the configuration setting. If the blood warmer is on the return line, you must enter the volume of the blood warmer tubing set, so that the system can adjust the volume of saline required to perform rinseback.

To select the procedure options, do the following:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Options** tab. The options screen appears.
3. Follow the instructions below to select the procedure options.
4. When you are finished selecting the options, touch **Confirm**.
5. Follow the instructions on the screen to continue the procedure.

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Selecting Rinseback

The default selection for rinseback is **Yes**. The system prompts you to perform rinseback at the end of the run.

If you do not want to perform rinseback, touch the button until **No** appears on the button. If you select **No** and decide later to perform rinseback, perform the following steps:

1. When the run targets screen appears, touch the **End Run** menu button.
2. Touch the **Rinseback** tab.
3. Follow the instructions on the screen to proceed with rinseback.

Selecting and Performing a Custom Prime

The system prompts you to enter data for the custom prime after it primes the tubing set and before you connect the patient. Two methods are available for selecting a custom prime:

- Select the custom prime option on the options screen. The custom prime option is available to select before you connect the patient.
- Accept the system's recommendation that you consider performing a custom prime. The system makes the recommendation based on the RBC volume and total blood volume limit specified in configuration, and the patient data that you entered. If you change the patient data and the system determines that a custom prime may no longer be necessary, it will display an alert.

If you perform a custom prime, you need the following supplies:

- Fluid for the custom prime
- Empty bag
- Filter or blood administration set (optional)
- Appropriate connectors to attach the inlet and return lines to the fluid and the empty bag

Selecting the custom prime option

To select the custom prime option, touch the custom prime button until **Yes** appears on the button.

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Accepting a custom prime recommendation

The system displays a screen after you enter the patient data recommending that you consider performing a custom prime. Perform the following steps:

1. Review the patient data and procedure configuration information on the screen, and confirm that it is correct. The screen also shows the percent of the patient's TBV and RBC volume in the tubing set.
2. To accept the recommendation, touch **Yes**. To decline the recommendation, touch **No**.

Entering data for the custom prime

If you select the custom prime option or accept a custom prime recommendation, the system prompts you to enter data for the custom prime. Perform the following steps:

1. Choose one of the following fluid types to use for the custom prime by touching the corresponding button on the screen:
   - RBC
   - Plasma
   - Albumin
2. Enter the fluid data by touching the corresponding buttons on the screen:
   - RBC unit Hct (%)
     - Available if you select RBC as the fluid type.
   - Maximum inlet flow rate (mL/min)
     - If you are using a filter, determine if the filter has a flow rate limit.
   - Volume (mL) of the custom prime fluid
     - Patient will not receive the full benefit of the custom prime if the volume entered is less than 200 mL plus the volume of the blood warmer tubing set, if you are using a blood warmer.
3. Touch **Confirm**.

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Starting the custom prime

1 Perform the steps that appear on the screen:

   a. Connect the inlet line to the container of fluid to use for the custom prime. Connect a filter, if indicated.

   b. Connect the return line to the empty bag.

   c. Unclamp the inlet line and the return line.

2 Touch **Start Custom Prime**. The status of the custom prime appears on the screen.

Note: Monitor the progress of the custom prime. If the actual volume in the container of custom prime fluid is less than the volume you entered on the screen, you may need to stop the custom prime before it is complete to avoid drawing air into the tubing set.

3 When the custom prime is complete, the screen appears instructing you to connect the patient lines.

Ending the custom prime before it is complete

1 Touch **End Custom Prime**. A screen appears on which you must confirm your decision to end the custom prime.

Note: If you end the custom prime before the system has processed 200 mL of volume, a screen appears informing you that the volume processed was not sufficient to complete the custom prime. Follow the instructions on the screen to resume or end the custom prime.

2 Touch **End Custom Prime**, and then touch **Confirm**.

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Extending the custom prime

You may extend the custom prime by increasing the volume entered for the fluid to use for the custom prime. To extend the custom prime, perform the following steps:

1. When the screen appears instructing you to connect the patient lines, touch the go back button. The screen appears that instructs you to prime the inlet and return lines. **Do not** perform the instructions on the screen.
2. Touch **Confirm**. The screen appears that prompts you to enter the fluid data.
   - If you decide not to extend the custom prime when you reach this screen, touch the **Options** tab. The options screen appears. Change the custom prime button to **No**, and touch **Confirm**.
3. Touch the volume button and enter the sum of the original fluid volume plus the volume of the additional fluid.

   For example, if the volume that you first entered for the custom prime was 250 mL and you decide to extend the custom prime by 30 mL, enter 280 mL.
4. Touch **Confirm**.
5. Touch **Start Custom Prime**.

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Selecting and Performing a Saline Rinse

The system prompts you to perform the saline rinse after it primes the tubing set and before you connect the patient. To select and perform a saline rinse, do the following:

1. To select the saline rinse option, touch the saline rinse button until **Yes** appears on the button. Resume the procedure.
2. When the screen appears with the message "Prepare for saline rinse," perform the steps that appear on the screen:
   a. Spike a new bag of saline that contains at least 250 mL, and squeeze the drip chamber to ensure that saline drips into the chamber.
   b. Connect an empty bag to the return line.
3. Touch **Continue**.
4. Perform the steps that appear on the screen:
   a. Wait 15 minutes to allow any residual ethylene oxide in the tubing set to diffuse into the saline.
   b. Open the inlet saline line and the return saline line.
   c. Unclamp the return line and flush the line to the access site with at least 50 mL of saline.
   d. Close the return saline line.
5. Touch **Start Saline Rinse**. The status of the saline rinse appears on the screen.
6. To stop the saline rinse before it is complete, touch **Cancel Saline Rinse**. A screen appears on which you must confirm your decision to cancel the saline rinse. Touch **End Saline Rinse**, and then touch **Confirm**.
7. After the saline rinse is complete, perform the steps that appear on the screen:
   - Close the inlet saline line
   - Clamp the return line.
8. Touch **Continue**. The screen appears instructing you to connect the patient lines.

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Indicating the Use of a Blood Warmer

Follow the instructions below to indicate the use of a blood warmer during the procedure. To connect and prime the blood warmer tubing, follow the instructions on the screens and in the Spectra Optia Apheresis System procedure guides.

Exchange procedures

1. Select the line on the tubing set to which you want to connect the blood warmer. To use more than one blood warmer, select both the return line and the replace line:
   - To indicate a blood warmer on the return line, touch the return line button until **Yes** appears on the button.
   - To indicate a blood warmer on the replace line, touch the replace line button until **Yes** appears on the button. Ensure you connect the blood warmer to the replace line before you spike the replacement fluid.
2. If you indicated a blood warmer on the return line, enter the volume of the blood warmer tubing set:
   a. Touch the tubing set volume button. A data entry pad appears.
   b. Enter the volume of the tubing set. The volume you entered appears on the button.

Collection procedures

1. Touch the return line button until **Yes** appears on the button.
2. Touch the tubing set volume button. A data entry pad appears.
3. Enter the volume of the blood warmer tubing set. The volume you entered appears on the button.

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6

Loading, Priming, and Removing the Tubing Set

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Loading the Tubing Set

Follow the instructions below to unpack the tubing set, load the set on the system, and test the set before you start the prime. These instructions apply to both the Exchange Set and the Collection Set.

Caution: **You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.**

Note: You must select the type of procedure that you want to perform before you load the tubing set. The system tests the tubing set to ensure that you are using the correct set for the procedure selected.

1. Verify that the tubing set has not expired by checking the expiration date on the cover of the package.
2. Touch **Prepare Tubing Set**. The screen appears instructing you to prepare the set.

Unpacking the Lines and Bags

Put the tubing set package on top of the centrifuge cover with the package label upright and facing you, and remove the cover from the package. Follow the instructions below according to the type of tubing set you are using.

Exchange Set

1. Take out the spike holder. The spike holder holds the replace line (white spikes), the AC line (orange spike), the saline line (green spike), and the extra remove line (yellow clamp). The remove bag with attached remove line is located inside the spike holder.
2. Take out the remove bag and the extra remove line, and put them on the right side of the centrifuge cover.
3. Take out the vent bag and hang the bag on the left side of the IV pole.
4. Remove the replace line and clamp one of the lines to the spikes. Put the line on top of the remove bag.
5. Take out the AC line (orange spike) and the saline line (green spike) and hang the lines over the left side of the system.
6. Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).

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7 Take out the cassette and the channel, and put them on top of the centrifuge cover.

8 Discard the empty tubing set package, according to your standard operating procedures.

Collection Set

1 Take out the product bags and the vent bag and put them on the right side of the centrifuge cover.

2 Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).

3 Take out the AC line (orange spike) and the saline line (green spike) and hang the lines over the left side of the system.

4 Take out the cassette and the channel, and put them on top of the centrifuge cover.

5 Discard the empty tubing set package, according to your standard operating procedures.

Loading the Cassette Into the Cassette Tray

1 Put the bottom of the cassette in the bottom edge of the tray (Figure 6-1).

Figure 6-1: Putting the cassette in the bottom edge of the tray

2 Ensure that there is nothing lodged behind the cassette or the tray that could interfere with the loading.

3 Press the top corners of the cassette to snap the cassette into the tray.

4 Hang the bags on the IV pole:

- If you are using an Exchange Set, hang the remove bag on the IV pole.
- If you are using a Collection Set, hang the bags from left to right on the IV pole in this order: Vent bag, Plasma bag, collection bag.

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Loading the Channel in the Centrifuge

1. Open the centrifuge door.
2. Locate the pin on the filler latch. Raise the latch by pushing the pin toward the center of the filler while pulling up the latch.
3. Turn the centrifuge so that the loading port faces you.
4. Fold the channel in half. If you are using a Collection Set, tuck the chamber inside the folded channel.
5. Push the channel up through the loading port and the opening in the center of the filler (Figure 6-2). Lower the filler latch and lock it in place.

Figure 6-2: Pushing the channel through the loading port (Collection Set shown here)

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6 Position the lower collar in the filler latch so that the pink line is not obstructed by the other lines (Figure 6-3).

7 Push the collar into the collar holder until you hear the "click" of the locking pin as it pops out and locks the collar in place. Ensure that the notch at the base of the locking pin is visible. If the collar is locked, you can see the notch (Figure 6-3).

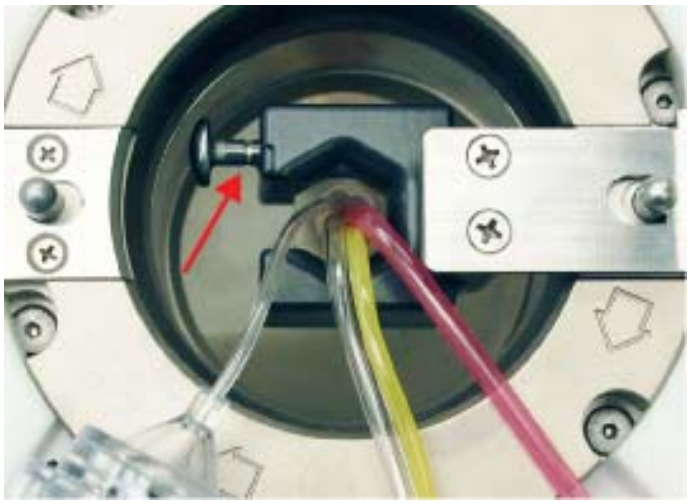

Figure 6-3: Lower collar correctly positioned and locked with the notch visible (Collection Set shown here)

8 Starting with the connector, insert the channel into the groove in the filler, finishing with the inlet port (Figure 6-4). Run your finger over the groove and push down any section of the channel that is not completely inserted in the groove. The channel must sit flush with the groove.

Figure 6-4: Pressing the channel into the groove (Exchange Set shown here)

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9 If you are using a Collection Set, put the chamber into the chamber bracket. Ensure that the chamber sits behind the clip at the opening of the bracket, so that the clip retains the chamber in the bracket. Put the collect line to the chamber behind the lip of the optical reference, so that the line does not block the optical reference (Figure 6-5).

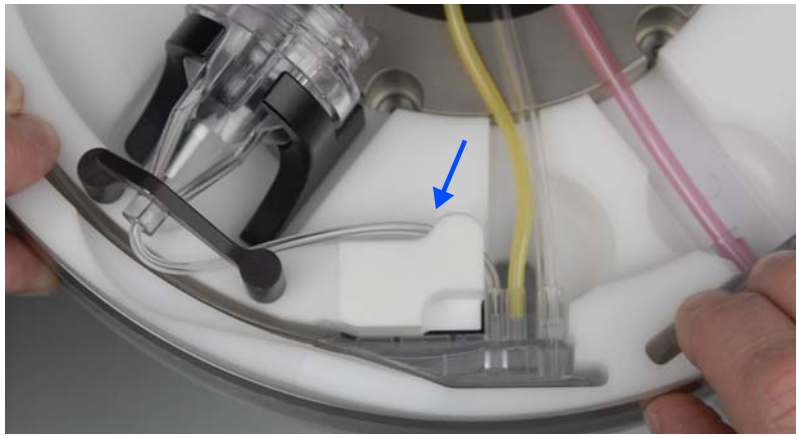

Figure 6-5: Correct position of the collect line to the chamber of the Collection Set

Loading the Lower and Upper Bearings, and the Upper Collar

1 Insert the narrow part of the lower bearing into the lower bearing holder, and the narrow part of the upper bearing into the upper bearing holder (Figure 6-6). Ensure that the braided section of the loop is not twisted.

Figure 6-6: Lower bearing inserted in the lower bearing holder (left) and the upper bearing inserted in the upper bearing holder (right)

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2 Position the upper collar below the upper collar holder and insert the line into the holder. Pull the line up to secure the upper collar in the holder (Figure 6-7).

Figure 6-7: Inserting the upper collar into the holder

3 Spin the centrifuge clockwise to ensure that it rotates freely.

4 Close the centrifuge door.

5 Touch **Load**. The system lowers the cassette.

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Testing the Tubing Set

If you are using an Exchange Set, begin at Step 1. If you are using a Collection Set, begin at Step 2.

1 If you are using an Exchange Set, follow the instructions on the screen to perform the following steps, and then go to Step 3:

a. Close the inlet saline line and the return saline line.

b. Clamp the extra remove line.

2 If you are using a Collection Set, follow the instructions on the screen to perform the following steps:

a. Clamp the line to the diversion bag. Close the inlet saline line and the return saline line.

b. Clamp the line to the sample bulbs.

3 Touch **Continue**.

4 Follow the instructions on the screens to clamp the inlet line and the return line.

5 Touch **Continue**. The system performs several tests to verify that the tubing set and system components function properly, and that the tubing set is loaded correctly.

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Priming the Tubing Set

This section describes how to prime the tubing set after you load and test the set.

1. Follow the instructions on the screen to perform the following steps:
   a. Spike the fluid containers.
   b. Fill the drip chambers.
   c. Insert the AC line in the AC fluid detector.
2. Touch **Start Prime**. The system primes the AC line.
3. Follow the instructions on the screen to open the inlet saline line and the return saline line.
4. Touch **Continue**. The system primes the return line, the inlet line, the RBC line, and the channel. The system primes the set in about 3 to 4 minutes. When the system finishes the prime it sounds a tone. The patient data screen appears.

   Note: The menu buttons at the top of the screen are active so that you may enter or change patient or procedure data during the prime.

5. Follow the instructions on the screen and in the appropriate Spectra Optia Apheresis System procedure guide to continue the procedure.

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Removing the Tubing Set

Once you finish the procedure and raise the cassette, perform the following steps to remove the tubing set:

1. Open the centrifuge door.
2. Remove the upper collar from the collar holder by grasping the lines above and below the collar, and pulling the lines downward.
3. Remove the upper and lower bearings from the bearing holders.
4. If you are using a Collection Set, remove the chamber from the bracket.
5. Gently pull the channel from the filler.
6. Push in the locking pin on the centrifuge collar holder and remove the collar from the holder by grasping the tubes above the collar and pulling upward.
7. Push the filler latch pin toward the center of the centrifuge, and raise the filler latch.
8. Fold the channel in half, and pull the channel through the loading port and out of the centrifuge chamber.
9. Lower the filler latch.
10. Close the centrifuge door.
11. Remove the lines from the fluid detectors.
12. Remove any bags from the IV pole.
13. Press the latch on the upper right corner of the cassette tray, and lift the cassette from the tray.
14. Discard the tubing set, according to your standard operating procedures.

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7

Troubleshooting

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Troubleshooting Alarms

The Spectra Optia system has independent control and safety systems that constantly monitor the performance of the system. If either system detects an operation error or a potentially unsafe operating condition, the system sounds an alarm and illuminates the warning lights on the front panel. The warning lights flash if the safety system detected the error. The system displays information about the alarm and troubleshooting instructions on the screen. Figure 7-1 shows an example of an active alarm screen, which appears if an alarm occurs. Figure 7-2 shows an example of an alarm action screen, which shows the steps to perform to resolve the condition causing the alarm. Tables 7-1 and 7-2 contain descriptions of the different sections of the screens.

The operator plays an essential role in the safe operation of the system. If an alarm occurs, it is crucial for the operator to consider all possible causes for the alarm and thoroughly read the instructions that appear on the screens to resolve the alarm. It is the operator's responsibility to determine if it is safe to continue the procedure, and to follow the appropriate instructions.

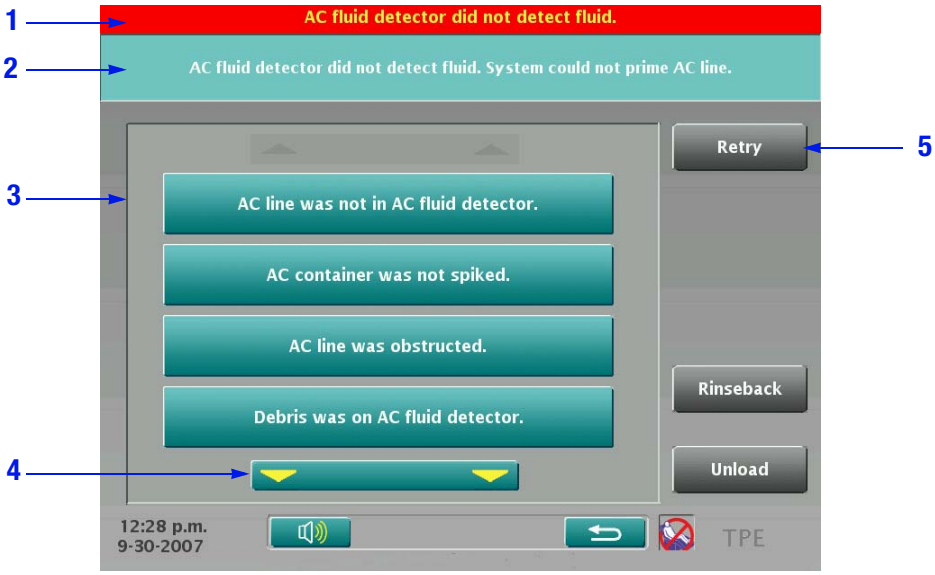

Figure 7-1: Example of an active alarm screen

Table 7-1: Descriptions of the sections on an active alarm screen

	Section	Description
1	Alarm name	States the name of the alarm that occurred.
2	Alarm explanation	Provides a brief explanation of the condition that caused the alarm.

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Table 7-1: Descriptions of the sections on an active alarm screen (continued)

	Section	Description
3	Possible causes	Lists the possible causes of the alarm in order of most likely (top) to least likely (bottom). Each possible cause is an active button that you can touch to display the action steps you should perform to resolve the condition causing the alarm.
4	Scroll button	Indicates that additional possible causes for the alarm condition exist. Touch the button to view the additional causes.
5	Action buttons	Displays buttons of available actions that you can touch to help resolve the condition. For details, read the action steps for the possible cause before you touch an action button.

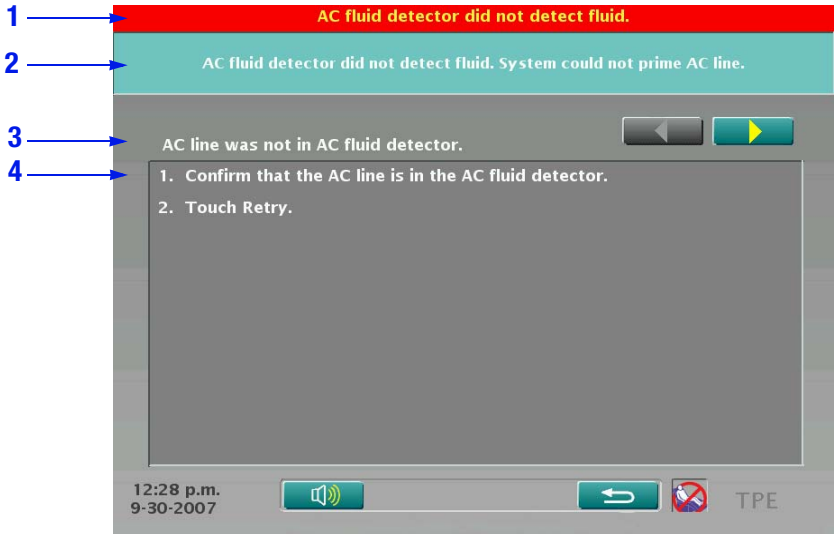

Figure 7-2: Example of an alarm action screen

Table 7-2: Descriptions of the sections on an alarm action screen

	Section	Description
1	Alarm name	States the name of the alarm that occurred.
2	Alarm explanation	Provides a brief explanation of the condition that caused the alarm.

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Table 7-2: Descriptions of the sections on an alarm action screen (continued)

	Section	Description
3	Possible cause	Shows the possible cause of the alarm, which was selected from the list on an active alarm screen.
4	Action steps	Shows the action steps to perform to resolve the condition causing the alarm.

If an alarm occurs, perform the following steps:

Note: If you want to silence the alarm sound, touch the mute button at the bottom of the screen.

1. Read the alarm name and the alarm explanation.
2. Read the list of possible causes for the alarm, and identify the most probable cause for the alarm.
3. Touch the button for the cause that you identified. The alarm action screen appears.
4. Follow the steps on the screen to resolve the condition causing the alarm.
5. If the actions for the cause you identified do not resolve the condition, repeat steps 2 through 4 until you resolve the condition. To view previous or subsequent alarm action screens, touch the scroll buttons. To return to the active alarm screen, touch the go back button.
6. If you are instructed to contact your service representative for assistance, write down the name of the alarm exactly how it appears on the screen. Be prepared to provide the name to your service representative.

Troubleshooting Multiple Alarms

To view a list of active alarms, do the following:

1. Touch the active alarm button at the bottom of the screen. The screen of active alarms appears with a list of active alarms.
2. Touch the button of the alarm that you want to troubleshoot.
3. To exit the screen, touch the go back button.

Note: You must resolve all conditions causing alarms before you can resume the procedure. The active alarm button appears at the bottom of the screen if there are additional conditions to resolve. Some conditions may resolve themselves when you troubleshoot other conditions, and as a result will disappear from the list of active alarms.

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Viewing Alarm History

1 Touch the **Data** menu button. The menu tabs appear.

2 Touch the **Alarm History** tab. The alarm history screen appears with a list of alarms that have occurred, including the time the alarm occurred.

3 To exit the screen, touch the go back button.

Muting the Alarm Sound

You may silence the alarm sound for 2 minutes by touching the mute button on the lower left corner of the screen. The system sounds a reminder tone every minute thereafter to remind you that there is an active alarm. If a new alarm occurs, the system restores the alarm sound.

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Managing Anticoagulation of the Extracorporeal Circuit

Caution: **Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit. The attending physician is responsible for prescribing the anticoagulant used, however, and all personnel involved in performing apheresis procedures should read the anticoagulant manufacturer's product insert before use.**

Proper anticoagulation of the system's extracorporeal circuit ensures that the flow of blood and fluid through the circuit is not obstructed during the procedure. Terumo BCT recommends that you use an inlet:AC ratio up to 15:1 when using ACD-A. The system's default inlet:AC ratio depends on the procedure selected. Refer to the Spectra Optia Apheresis System procedure guides for the default ratios. You may need to use a different ratio, however, for a patient with a unique hematologic condition. If the circuit is not adequately anticoagulated, Platelet aggregates or clots may form, and eventually cause an obstruction in one or more of the following areas:

- Filter at the bottom of the reservoir
- Remove line (Exchange Set)
- Collect line or Plasma line (Collection Set)
- Lines in the centrifuge, which can result in an unstable interface

To eliminate the aggregates or clots, decrease the inlet:AC ratio. If an alarm occurs indicating a possible obstruction, follow the instructions on the alarm action screen, and monitor the system for the rest of the procedure. If you do not eliminate the obstruction, the system may require that you discontinue the procedure.

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Handling Fluid Leaks

The fluid leak detector is a strip of moisture-sensitive material running down the back wall and floor of the centrifuge chamber. If it detects moisture inside the centrifuge chamber, or if it is not functioning correctly, an alarm occurs.

1. If you do not see signs of blood or moisture, clean the fluid leak detector with an alcohol pad using a gentle side-to-side motion. Then dry the detector with a clean cloth or gauze pad.

   Note: Refer to "Disinfecting the System" on page 85 for instructions on disinfecting the Spectra Optia system after leaks or spills.

2. If you see a fine spray of blood or moisture on the inside walls of the centrifuge chamber, a small leak exists. Do one of the following to discontinue the procedure:
   - If the patient is not connected and the cassette is lowered, touch **Unload** and unload the tubing set.
   - If the patient is connected and the procedure is in progress, touch **Rinseback**.
   - If rinseback is not an option, touch **Disconnect**.
3. If you see a pool of blood in the centrifuge chamber, touch **Disconnect** and disconnect the patient.

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Resuming a Procedure After a System Reset

The system resets itself under the following conditions:

- Power to the system fails and is then restored.
- You touch **Reset**, according to instructions on an alarm screen.
- An alarm condition causes the system to reset itself.
- You turn the system off and then on again.

After the reset, the system performs a series of tests to ensure that it is safe to resume the procedure. A screen appears with instructions for how to proceed after the reset. Do the following:

1 Follow the instructions on the screen to resume the procedure at the point before the reset occurred. You may also choose to discontinue the procedure.

- If the reset occurred during a run and you chose to continue the procedure, a screen appears asking you to ensure that both saline lines are closed. Follow the instructions on the screen to confirm that the lines are closed.
- If an alarm was active when the reset occurred, the action buttons that appear on the screen will be the same as the buttons that were available on the alarm screen. If the alarm condition still exists after you complete the instructions on the screen, the alarm will recur.

2 Verify that the system restored the patient and procedure data you entered before the reset occurred. The system restores the data only if the tubing set cassette was in the lowered position when the reset occurred.

- If the reset occurred before you started a custom prime, the system does not restore the custom prime data. Go to the screen that instructs you to enter the custom prime data and re-enter the data.

3 Verify that you completed the task that appeared on the screen before the reset occurred. Depending on when the reset occurred, you may need to repeat a sequence of steps.

- If the reset occurred during administration of a fluid bolus, the system discontinued the bolus. Go to the exchange status screen to view the volume that the system administered.

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Performing a Manual Rinseback

Important: You should read and understand these instructions before you attempt to perform a manual rinseback.

If you are not able to complete a procedure due to an alarm condition, a power interruption, or a system malfunction, you may choose to perform a manual rinseback. Perform the following steps to complete a manual rinseback.

Sealing and clamping the lines

1. Clamp the inlet and return lines.
2. Close the saline lines.
3. Disconnect the inlet line from the patient.
4. Seal the AC line.
5. If you are using an Exchange Set, seal the remove line and the replace line.
6. If you are using a Collection Set, seal the collect line and the Plasma line.

Note: Ensure that you do not seal the line to the vent bag. If you seal the line, you will not be able to resume the manual rinseback.

7. Turn off the Spectra Optia system.

Draining the channel

1. Open the centrifuge door. If the door does not open, follow the instructions on page 77 to manually open the door.
2. Remove the channel from the filler and hang it on the IV pole with the inlet line at the highest point, so that the fluid in the channel drains into the cassette reservoir.

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3 Ensure that the RBC valve is in the return position (Figure 7-3), or the fluid will not drain.

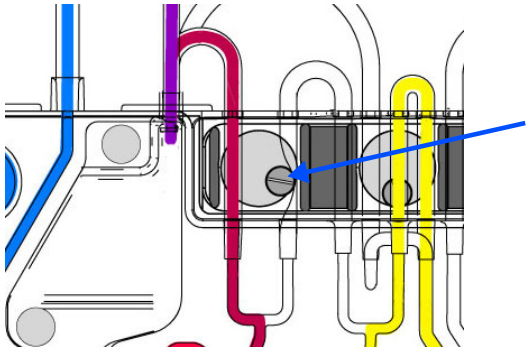

Figure 7-3: RBC valve in the return position (Exchange Set shown here)

Returning the Fluid to the Patient

1 Remove the rotor from the return pump:

a. Push in the rotor and turn it to the left to unlock.

b. Pull the rotor off the pump.

2 Use a hemostat to clamp the RBC line directly below the cassette (Figure 7-4).

Note: Do not seal the RBC line instead of clamping it. If you seal the line, the tubing set could leak when you raise the cassette to unload the set.

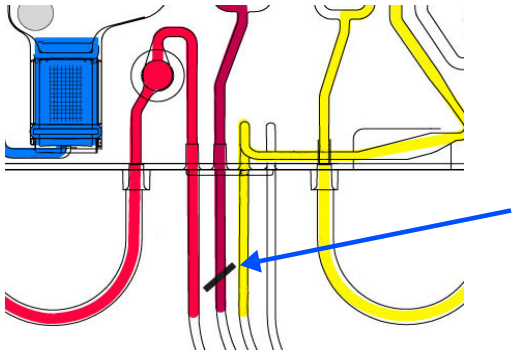

Figure 7-4: Where to clamp the RBC line (Exchange Set shown here)

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3 Unclamp the return line (Figure 7-5).

Figure 7-5: Return line unclamped

4 Gently squeeze the vent bag to push the fluid from the reservoir to the patient. This should take several minutes to complete. Do not try to expedite this process by applying more pressure to the bag.

Warning: Do not apply excess pressure to the vent bag when pushing fluid from the reservoir to the patient during a manual rinseback or you could damage the Red Blood Cells that you are returning to the patient.

5 When the level of fluid in the reservoir drops to the level of the reservoir filter (Figure 7-6), clamp the return line and stop squeezing the vent bag.

Warning: Do not continue to squeeze the vent bag after the fluid in the reservoir reaches the level of the reservoir filter during a manual rinseback. If you continue to squeeze the bag, you could deliver air to the patient.

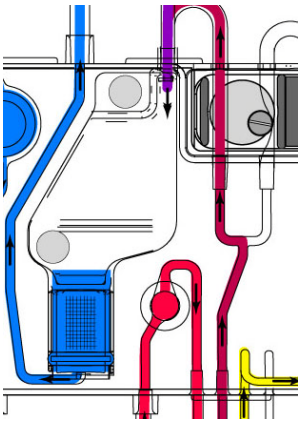

Figure 7-6: Level of fluid in the reservoir at the level of the reservoir filter (Exchange Set shown here)

6 Disconnect the patient.

7 Remove the hemostat from the RBC line. Ensure that you do this before you raise the cassette in step 9, or the return pressure sensor will leak.

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8 Replace the rotor on the return pump:

a. Pull the tubing out of the pump housing and down toward the cassette.

b. While holding the return pump tubing in the position described in step a., push the rotor back in the housing.

9 If the system functions, perform the following steps:

a. Turn on the system.

b. Touch **Disconnect** to discontinue the procedure.

c. Touch **Unload** to raise the cassette.

d. Unload the tubing set.

10 If the system does not function, manually raise the cassette according to the instructions on page 78, and then unload the tubing set.

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Manual Method for Opening the Centrifuge Door and Raising the Cassette

If the power to the system is interrupted when the centrifuge is spinning, or the system does not function correctly, the pumps stop and the centrifuge door may not open. To unload the tubing set, you need to manually open the centrifuge door and raise the cassette.

Manually Opening the Centrifuge Door

1. Confirm that the system is turned off. Unplug the system from the power source.
2. Remove the cap from the centrifuge door lock-release hole, which is located near the top-right corner of the centrifuge door.
3. Insert the centrifuge door key or a long, thin, metal rod into the lock-release hole (Figure 7-7). Push in the key until you hear a click.

Note: Do not use a cotton swab, stick, or other breakable object to manually open the centrifuge door, as it may break and jam the door.

Figure 7-7: Centrifuge door key in the lock-release hole

4. Remove the key.
5. Squeeze the centrifuge door handle and gently lower the door. Replace the cap into the lock-release hole.

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Manually Raising the Cassette

If a system malfunction occurs and you must turn off the Spectra Optia system, you can manually raise the cassette to remove the tubing set. To raise the cassette and open the valves, perform the following steps.:

Warning: Do not touch Unload to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

1. Confirm that the patient is disconnected.
2. Seal or clamp the lines to the fluid containers.
3. Unplug the system from the power source.
4. Turn each valve to the neutral position using a flat-blade screwdriver (Figure 7-8).

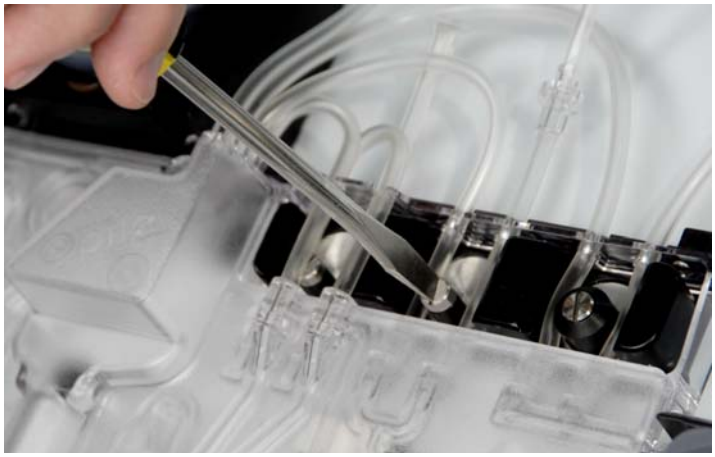

Figure 7-8: Valves turned to the neutral position

5. Remove each pump rotor from the pumps:
   a. Push in the rotor and turn it to the left.
   b. Pull the rotor off the pump.

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6 Insert the screwdriver into the small hole in the vent on the back of the system (Figure 7-9) until you engage the slotted end of the pin attached to the back of the cassette tray. You may need to angle the screwdriver to locate the pin.

Figure 7-9: Screwdriver inserted n the hole in the back of the system

7 Turn the screwdriver counterclockwise until it no longer turns, and the cassette tray is in the fully raised position.

8 Follow the instructions on page 64 to remove the tubing set from the system.

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Maintaining the Spectra Optia System

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Cleaning the Spectra Optia System

Clean the Spectra Optia system after every procedure and on a weekly basis. Other than to ensure that the system is clean and undamaged before use, you are not required to perform system maintenance.

Warning: Turn off the system before cleaning to prevent possible electrical shock or damage to the equipment.

Caution: Clean the Spectra Optia system using a mild cleaning solution, or a mild detergent. Industry standard practice defines mild detergent as a solution or detergent that is safe on skin and on washable surfaces, such as hand dishwashing liquid. Use of a solution that is not compatible with the materials on the system may damage the material or operating characteristics of the system.

The information in this section explains the recommended cleaning frequency and cleaning procedures for the Spectra Optia system, including:

- Routine cleaning after every procedure
- Weekly cleaning
- Periodic cleaning

Routine Cleaning After Every Procedure

Warning: When cleaning and disinfecting equipment surfaces that might have been exposed to blood, take adequate precautions to prevent possible exposure to and transmission of infectious diseases.

Clean the surfaces and the touch screen of the Spectra Optia system to remove all traces of dirt and fluid, using a solution of mild detergent and water, and a clean cloth or gauze pad. In case of a blood spill, follow the instructions under “Disinfecting the System.”

Weekly Cleaning

Clean the sensors, the detectors, and the valves on the front panel of the Spectra Optia every week, according to the instructions below.

Cleaning the sensors and the detectors

Fluid spilled on the sensors and the detectors could interfere with the system operation and may not be visible. It is important to clean the sensors and the detectors weekly and after any spill.

Use a gauze pad or cotton swab dampened with water to clean the sensors and detectors. Terumo BCT recommends using distilled water on sensors and detectors. Do not use detergent

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to clean the sensors and detectors because detergent may leave a film residue if it is not thoroughly removed. Dry the RBC detector immediately after cleaning.

Caution: Do not spray or douse the Red Blood Cell (RBC) detector with liquid to clean it. Using an excessive amount of liquid can damage the detector. If you must spray the front panel, cover the RBC detector beforehand.

Cleaning the valves

Clean the surfaces of the valves using a solution of water and mild detergent, and a cotton swab.

Periodic Cleaning

Cleaning the pump housings and pump rotors

Perform the following steps to clean the pump housings and pump rotors:

1. Remove each pump rotor from the housing:
   a. Push in the rotor and turn it to the left (Figure 8-1).
   b. Pull out the rotor from the housing.

Figure 8-1: Removing the rotor from the pump housing

2. Clean the housing and the rotor using a solution of mild detergent and water, and a clean cloth or gauze pad. Allow the surfaces to air dry before you replace the rotor.

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3 Align the rotor with the housing. Ensure that the metal bar in the housing aligns with the corresponding slot in the rotor. Push in the rotor and turn it to the right to lock the rotor in place. If you do not properly install the rotor, an alarm will occur the next time you load a tubing set.

Note: Ensure that you install the rotor with the black dot in the housing for the replace/collect pump.

Cleaning the fluid leak detector

The fluid leak detector is a strip of moisture-sensitive material that runs down the wall and floor of the centrifuge chamber. To clean the detector of dirt or debris, wipe it with an alcohol pad. To clean the detector after a large fluid spill, do the following:

1 Using a clean cloth and a solution of mild detergent and water, wipe the surface along the ridges of the detector using a gentle, side-to-side motion. Be careful not to damage the ridges of the detector. Cleaning with mild detergent and water removes organic material, including oils.

2 Allow the detector to air dry.

3 Wipe the detector with water to remove any residue.

4 Dry the detector with a clean cloth or gauze pad.

Cleaning the glass covers on the lights in the centrifuge chamber

Debris on the glass covers of the lights on the top and bottom of the centrifuge chamber can affect the function of the AIM system. To clean the covers, do the following:

1 Wipe the surfaces of the covers using water and a gauze pad or other lint-free cloth.

2 Allow the covers to air dry.

3 Wipe the covers again with water to remove any residue.

4 Dry the covers with a gauze pad.

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Disinfecting the System

Use a 0.25% sodium hypochlorite (bleach) solution, consisting of 1 part 5.25% to 6.0% commercial household bleach diluted with 18 parts water, to disinfect any portion of the Spectra Optia system that comes in contact with blood. For maximum effectiveness, the solution should be prepared the day it is used.

Caution: **Disinfect the Spectra Optia system using a 0.25% sodium hypochlorite (bleach) solution. Use of a stronger bleach solution may damage or discolor the system.**

Note: The bleach solution may leave streaks on the screen. A mild, non-abrasive detergent or water can be used to remove the streaks.

If a blood spill occurs, check the following areas and disinfect them, according to your facility's standard operating procedures:

- System surface
- Front Panel
- Centrifuge chamber

Disinfecting the Surface of the System

Use a clean cloth, gauze, or cotton swab dampened with freshly prepared bleach solution to disinfect the surface of the Spectra Optia system. Allow the surface to air dry.

Disinfecting the Front Panel

To disinfect the sensors, detectors, valves, pump housings, and pump rotors on the front panel, follow the instructions under "Weekly Cleaning" on page 82, and "Periodic Cleaning" on page 83, substituting the bleach solution for the water or mild detergent.

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Disinfecting the Centrifuge Chamber

A blood spill may occur in the centrifuge chamber. Cleaning a spill inside the centrifuge chamber is the operator's responsibility, unless the blood is in an area that cannot be cleaned without disassembling the machine. In that case, contact your service representative for assistance.

Disinfecting the fluid leak detector and the glass covers on the lights

Follow the instructions under “Cleaning the fluid leak detector” and “Cleaning the glass covers on the lights in the centrifuge chamber” on page 84, substituting the bleach solution for mild detergent and water.

Removing and disinfecting the filler

1. Open the centrifuge door by grasping the handle and pushing upwards with your fingers to release the lock.
2. Push the filler latch pin (Figure 8-2, number 1) toward the center of the centrifuge and raise the filler latch.
3. Push the filler locking pin (number Figure 8-2, number 2) toward the center of the centrifuge. With the pin pushed in, grasp the edge of the filler and lift up to raise the filler off the centrifuge.

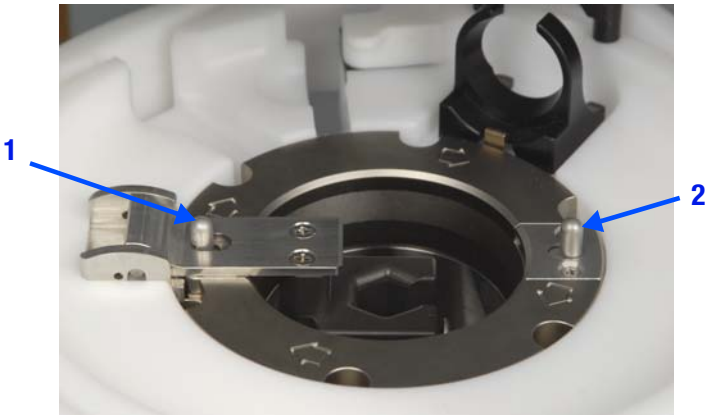

Figure 8-2: Locations of the filler latch pin (1) and the filler locking pin (2)

4. Wipe the filler using bleach solution and a clean cloth or gauze pad. Use a cotton swab to clean the groove of the filler, and a dry swab or alcohol pad to remove excess fluid. Allow the filler to air dry.

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Installing the filler

1 Align the two notches on the bottom of the filler with the two metal pins on the centrifuge (see Figure 8-3), and firmly press the filler down until the filler locking pin is securely in place. You should hear a click when the pin is in the correct position.

Figure 8-3: Aligning the notches on the filler with the pins on the centrifuge to install the filler

2 Verify that the filler is secure by pulling it upwards. If the filler is properly locked, it should remain firmly in place.

3 Lower the filler latch.

4 Close the centrifuge door.

Performing Preventive Maintenance

To prolong equipment life and to ensure maximum performance of the Spectra Optia system, a qualified service technician should calibrate the system and perform preventive maintenance every 6 months, with a compliance window of ±30 days from the scheduled date of the maintenance. Contact your Terumo BCT representative for more information.

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9

Spectra Optia System Specifications

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Spectra Optia System Specifications

General System Specifications

Electrical

Table 9-1: Electrical power and safety

Characteristics	Performance	Conditions
Electrical power requirements	100 to 240 Vac 10 to 4 A 50/60 Hz	Where a circuit breaker provides excess current protection
Ethernet connection	Connector is electrically isolated	• Location where a device can be connected to the system to print reports • Location where service personnel can connect to the system to download procedure information to a computer when a patient is not connected
Safety certifications	Meets the requirements of EN 60601-1 and EN 61010-2-20	CE Marking
	Device is certified by CSA International in accordance with applicable U.S. and Canadian standards. For applicable standards for the product, see Table 9-19 on page 99.	CSA Certification to applicable U.S. and Canadian standards
	Meets the requirements of category IP21 of IEC 60529	

Environmental

Table 9-2: Environmental

Characteristics	Performance	Conditions
Ambient operating temperature	15.5 °C to 27.7 °C (60 °F to 82 °F)	
Ambient operating humidity	8% to 80%	Relative humidity (RH), noncondensing

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Table 9-2: Environmental (continued)

Characteristics	Performance	Conditions
Cleaning	Surface of the device can be cleaned and disinfected; pump rotors can be removed for cleaning; channel leaks are contained within the centrifuge chamber, and chamber can be cleaned and disinfected.	Device is not damaged by cleaning and disinfecting with water, mild detergent, or a 0.25% sodium hypochlorite solution, as described in Chapter 8.
Access by foreign material	Device is protected against access by foreign objects and falling water.	
Restrictions	Device is not for use in an explosive atmosphere.	
Shipping/storage temperature	0 °C to 60 °C (32 °F to 140 °F)	
Shipping/storage humidity	8% to 80%	Relative humidity (RH), non-condensing

Physical

Table 9-3: Physical

Characteristics	Performance	Conditions
Floor space required	0.43 m^2 (4.6 ft^2)	Applies to a floor slope of less than 5°
Minimum clearance	30 cm (11.8 in) around the perimeter of the device	
Height	• 106.4 cm (41.9 in) (without the IV pole) • 162.1 cm (63.8 in) (with the IV pole)	
Width	52.7 cm (20.75 in)	
Depth	81.3 cm (32.0 in)	
Weight	92 kg (202 lb)	

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Sound level

Table 9-4: Operating sound level

Characteristics	Performance	Conditions
Average sound level during the run state	68 dBA to 70 dBA	Normal run conditions

System Components

Centrifuge

Table 9-5: Centrifuge speed and g-force

Characteristics	Performance	Conditions
Maximum centrifuge speed	3000 rpm	
Maximum g-force in the channel	1200 g	Device is operating at the maximum speed.

Pumps

Table 9-6: Pump flow rates

Characteristics	Performance	Conditions
AC pump	Up to 12 mL/min	When a patient is connected
Inlet pump: • Exchange procedures • Collection procedures	 • Up to 142 mL/min • 10 to 125 mL/min	
Plasma pump: • Exchange procedures • Collection procedures	 • Up to 142 mL/min • Up to 125 mL/min	
Collect pump (collection procedures): • During the run • During a chamber flush	 • Up to 150 mL/min • 1 to 15 mL/min	

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Table 9-6: Pump flow rates (continued)

Characteristics	Performance	Conditions
Replace pump (exchange procedures): • During the run • During a bolus	• Up to 150 mL/min • 10 to 120 mL/min	Characteristic of the flow rate range for administration of a bolus represents the range available to the operator.
Return pump: • During the run • During rinseback	• Up to 295 mL/min • 2 to 100 mL/min	Characteristic of the flow rate range for rinseback represents the range available to the operator.
Fluid balance accuracy during exchange procedures	± 8% of commanded balance	Normal operating conditions with no line restrictions. Pump accuracy can be affected by the temperature and viscosity of fluids.
Volume accuracy, all pumps	± 6% of displayed value	Normal operating conditions with no line restrictions. Pump accuracy can be affected by the temperature and viscosity of fluids.

Sensors and Detectors

Table 9-7: Anticoagulant and replacement fluid detectors

Characteristics	Performance	Conditions
Time to alarm	< 2 seconds after sensing the absence of fluid. An alarm is generated when the sensor is unloaded after fluid is present.	

Table 9-8: Centrifuge pressure sensor

Characteristics	Performance	Conditions
Operating range	400 to 2000 mmHg	
Alarm point	1350 mmHg	Accuracy ± 10%

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Table 9-9: Fluid leak detector

Characteristics	Performance	Conditions
Detection sensitivity	Detects fluid leaks when moisture reaches the wall or bottom of the chamber. Capable of detecting a 0.5 mL drop of fluid in the centrifuge.	Normal operating conditions

Table 9-10: Inlet and return pressure sensors

Characteristics	Performance	Conditions
Operating range	-300 to +500 mmHg	
Default alarm point: • Inlet pressure sensor • Return pressure sensor	 • -250 ± 30 mmHg • +400 ± 37 mmHg	
Accuracy	± 6% of the sensor reading or ± 20 mmHg, whichever is greater	

Table 9-11: Red Blood Cell detector

Characteristics	Performance	Conditions
RBC detection level	> 1.5% hematocrit	During a TPE procedure, the system automatically diverts the fluid away from the remove bag when it detects RBC. During an MNC collection procedure, the system initiates a collection phase when it detects RBC exiting the chamber.

Table 9-12: Low-level and high-level reservoir sensors

Characteristics	Performance	Conditions
Pump stroke volume between sensors	49 ± 9 mL. Sensors detect foam as air.	Level sensor requires a load force of > 5 lb (2.3 kg) each (> 10 lb [4.5 kg] total).
Alarm occurrence	When fluid is not detected at the low-level sensor, the sensor stops the pumps before air enters the line.	System performs a duplicate (redundant) safety check.

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Touch screen

Table 9-13: Touch screen

Characteristics	Performance	Conditions
Graphical user interface (GUI) touch screen.	Monitor holds a touch screen that provides tactile operator interface. Includes a speaker for alarms, alarm lights, and two external dedicated buttons with icons (stop button and pause button).	Screen is touched to cause a change in resistance.
Size	26.7 cm (10.5 in) diagonal measurement	
Screen type	Color, liquid crystal screen (LCD). Monitor holds backlight bulbs, which a service representative can replace when necessary.	

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System Software

Safety system

Table 9-14: Safety system

Characteristics	Performance	Conditions
Alarms	Audio alarm (mutable), steady red light, flashing red light, alarm screen	Light flashes if a Safety system alarm occurs; light is steady if a Control system alarm occurs.
Safety	No single-point of failure causes injury to the patient or the operator.	

Alarms

Table 9-15: AC infusion rate alarm

Characteristics	Performance	Conditions
Detection method	AC infusion to patient > limit specified by the operator, averaged over the system filling and emptying the reservoir one time	AC infusion rate is too high.

Table 9-16: AC pump flow rate alarms

Characteristics	Performance	Conditions
Detection method	• AC pump overspeed • AC flowing directly to the patient • Inlet:AC ratio is too low • Inlet:AC ratio is too high	• AC pump speed > 120 rpm. Pump stopped within two revolutions. • AC pump flow rate > inlet pump flow rate for more than 0.4 mL net AC pumped to the patient • System calculated inlet:AC ratio > 20% below the operator-specified value for 2 mL of inlet volume • System calculated inlet:AC ratio > 20% above the operator-specified value for 10 mL of inlet volume
Delay time	< 5 cycles of occlusion	

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Table 9-17: Inlet:AC ratio alarms

Characteristics	Performance	Conditions
Detection method	• AC ratio < 20% below the configured value • AC ratio > 20% above the configured value	• AC ratio is too low. • AC ratio is too high.
Delay time	Alarm occurs when either of the above conditions is met during the run until rinseback begins.	

Tubing Sets

Exchange Set and Collection Set

Table 9-18: Exchange Set and Collection Set

Characteristics	Performance	Conditions
Extracorporeal blood volume (approximate): • Exchange Set • Collection Set	• 185 mL • 191 mL	
Remove bag volume	6 L	Bag is on the Exchange Set only.
Collection bag volume	940 mL	Bag is on the Collection Set only.
Reservoir volume: • Between the high and low level sensors • Entire reservoir	• 49 mL • 56 mL	Reservoir prevents > 0.5 mL of air from entering the return line.
Sterile barrier filters	0.2 microns. Maintain functionally closed system.	Filters are on the saline, AC, and accessory lines of the Collection Set only.
Reservoir filter	Prevents particles (200 microns or larger) from entering the line at the bottom of the reservoir	
Inlet line trap	Traps large particles	
AC check valve	Prevents the free flow of AC through the tubing set	

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Table 9-18: Exchange Set and Collection Set (continued)

Characteristics	Performance	Conditions
RBC residual volume: • Rinseback performed • No rinseback performed	• ± 10 mL • Extracorporeal blood volume of the tubing set multiplied by the patient's Hct	Normal operating conditions
Channel life: • Exchange Set • Collection Set	• 6 hours • 8 hours	Normal operating conditions

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Symbols and Certifications

The symbols shown in Table 9-19 may appear on the Spectra Optia system, as applicable.

Table 9-19: Spectra Optia system symbols and certifications

Symbol	Definition
CE 0086	Indicates that the device is manufactured in conformance with the European Council Directive 93/42/EEC of June 14, 1993, concerning medical devices. This mark with the Notified Body Number 0086 indicates the approval by the British Standards Institute for these devices within the European Community.
C US	Indicates that the device is certified by CSA International in accordance with applicable U.S. and Canadian standards for conformance with the requirements of CAN/CSA-C22.2 No. 601-1-M90, CAN/CSA-C22.2 No. 1010.2.20-94, and UL 60601-1, as well as the applicable respective amendments to these standards.
	Indicates that the device is classified as type BF applied part, according to the safety standard IEC/EN 60601-1. This classification is based on the degree of protection against electrical shock, as defined in the standard.
	Indicates that the user must read the accompanying documents before operating the device to ensure safe operation.
IP21	Indicates that the device is protected against access by solid objects and falling water, as defined in standard IEC 60529.
	Indicates that the device requires an alternating supply current.
	Indicates a protective conductor terminal. Located near the chassis' grounding locations.
	Indicates a protective earth ground. Located near the chassis' grounding locations.

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Table 9-19: Spectra Optia system symbols and certifications (continued)

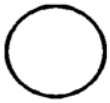
Symbol	Definition
	Indicates that the main power is turned on.
	Indicates that the main power is turned off.
	Indicates WEEE Directive: Product complies with waste electrical and electronic equipment directive 2002/96/EC (WEEE).
	Indicates that the product is non-pyrogenic.
	Not for Reuse: Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.
	Indicates the manufacturer of the product when accompanied by the name of the manufacturer.
	Indicates the date of manufacture (or sterilization date, if the product is sterile) when accompanied by a specific date.
	Indicates the authorized representative of the manufacturer when accompanied by the name of the representative.

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Table 9-19: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
	Indicates the product quantity when the quantity is placed in the square.
	Indicates the lot of the product when accompanied by a number.
	Indicates the expiration date of the product when accompanied by a specific date.
	Indicates a sterile fluid pathway using ethylene oxide (EtO).
Rx Only	Indicates that the use of product is by prescription only.
	Indicates the product catalog number when accompanied by a number.
	Indicates that the user must read the instructions for use before application.
	Indicates that the product must be kept away from sunlight.
	Indicates that the product must be kept dry.

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Table 9-19: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
	Indicates that the product packaging complies with European Directive 94/62/EC for packaging and packaging waste.
PHT DEHP	Indicates that the product contains phtalates, specifically Di(2-ethylhexyl) phtalate (DEHP).

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10

Seal Safe System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Seal Safe System Description and Components

Caution: Use the Seal Safe system only on tubing distributed by Terumo BCT. The Seal Safe system may not perform as expected on other tubing.

The Seal Safe system is designed to seal tubing that is distributed by Terumo BCT. The system generates a radio frequency (RF) electromagnetic field between the jaws of the sealer head to seal the tubing. The Seal Safe system consists of the following components:

- Sealer head
- Holder for the sealer head
- RF cable
- RF generator (inside the Spectra Optia system)
- Disposable splash guard (optional)

Installing the Seal Safe System

The Seal Safe system rests in a holder on the front panel of the Spectra Optia system. To install the device, do the following:

1. Attach one end of the RF cable to the connector on the Spectra Optia system, and the other end of the cable to the connector on the sealer head. Turn the ends of the cable clockwise on the connectors to lock them in place.
2. Attach a disposable splash guard to the sealer head, if required. For instructions on attaching a splash guard, see page 110.
3. Put the sealer head into the holder. The device is now ready to use.

Caution: To avoid possible damage to the Seal Safe system, always disconnect the sealer head and the RF cable before transporting the Spectra Optia system.

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Operating the Seal Safe System

Perform the following steps to operate the Seal Safe system:

Warning: Ensure that the sealer head and the tubing are free of moisture and debris before using the Seal Safe system.

Warning: Do not seal the tubing within 8 cm (3 in) of the needle, or you may cause a burn at the needle entry point.

Warning: Do not place your fingers within 2.5 cm (1 in) of the Seal Safe system's sealing jaw, or you may receive a radio frequency (RF) burn.

1 Hold the sealer head in the palm of your hand with your fingers on the plastic cover of the lever, so that the jaws open facing upward and you can see the indicator light on the head (Figure 10-1).

Figure 10-1: Hold the sealer head with jaws open facing upward

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2 Place the tubing into the jaw of the head and squeeze the lever until the jaw is completely closed and the indicator light illuminates (Figure 10-2).

Figure 10-2: Hold the jaw closed until the indicator light illuminates

3 After the indicator light goes off, hold the jaw closed for one second, and then release the lever.

4 Remove the tubing and inspect the integrity of the seal.

5 Put the sealer head back into the holder on the Spectra Optia system.

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Cleaning the Seal Safe System

This section contains instructions on how to clean the system. You are required to perform only periodic cleaning of the Seal Safe system.

Cleaning the Jaw Cavity of the Sealer Head

Debris or fluid in the jaw cavity of the sealer head impairs the performance of the device. If the jaw cavity becomes contaminated, clean it immediately by performing the following steps:

1. Disconnect the sealer head from the RF cable.

Warning: Disconnect the sealer head from the RF cable before cleaning to avoid receiving a serious radio frequency (RF) burn during the cleaning process.

2. Remove and discard the splash guard, if used.
3. Clean the jaw cavity with alcohol applied to a cotton swab. Do not use bleach solution to clean the cavity (Figure 10-3).

Figure 10-3: Clean the jaw cavity with a cotton swab

4. Clean all areas outside the jaw cavity. Squeeze the lever to expose areas outside of the cavity, and clean those areas.
5. Dry all parts of the jaw and jaw cavity.
6. Reconnect the RF cable, and put the sealer head back into the holder on the Spectra Optia system.

Note: If you are unable to satisfactorily clean the jaw cavity by performing the steps above, proceed to the instructions below for cleaning the sealer head.

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Cleaning the Sealer Head

The sealer head can be easily disassembled to allow for thorough cleaning and disinfection. Follow the instructions below to disassemble, clean, and reassemble the sealer head.

Disassembling the sealer head

1. Disconnect the RF cable from the sealer head.
2. Remove and discard the splash guard, if used.
3. Hold the sealer head in a vertical position with the jaw end pointing upward, and use your thumb to depress the jaw to the closed position. Do not squeeze the lever. For additional leverage, place the bottom of the of sealer head on a padded surface (Figure 10-4).

Figure 10-4: Depressing the jaw to the closed position

4. Remove the lever by slightly releasing the jaw and pulling the lever down and back (Figure 10-5).

Figure 10-5: Removing the lever

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5 Remove the jaw by pulling it up and sideways (Figure 10-6).

Figure 10-6: Removing the jaw

Cleaning the components of the sealer head

1 After you disassemble the sealer head, clean the components with alcohol applied to a cotton swab. Do not use bleach solution to clean the components.

2 Dry the components with a soft cloth.

3 Reassemble the sealer head, according to the instructions below.

Reassembling the sealer head

1 Ensure that the spring is in place in the head.

2 Locate the grooves on both sides of the head. Align the jaw with the grooves and slide it down the sealer head until it touches the spring (Figure 10-7). Ensure that the spring fits into the indentation in the jaw.

Figure 10-7: Aligning the jaw with the grooves

3 Use your thumb to slightly depress the jaw. Ensure that the spring stays in place.

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4 Replace the lever by tipping it at a 45° angle and positioning the lever pivots behind and below the pivot slots (Figure 10-8).

Figure 10-8: Replacing the lever

5 Push down the lever to engage the lever pivots while simultaneously depressing the jaw with your thumb.

6 Release your thumb. The lever should fully engage and secure the jaw on the sealer head.

7 Squeeze the lever to ensure that the head mechanically functions. If the jaw does not completely close, check the position of the spring.

8 Attach a clean splash guard, if required.

9 Reconnect the RF cable, and put the sealer head back into the holder on the Spectra Optia system.

Attaching a Splash Guard

1 Disconnect the RF cable from the sealer head.

2 Prepare a new splash guard:

a. Remove the perforated inset from one side of the splash guard (Figure 10-9).

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b. Fold the other inset inward at a 90° angle to form a clip (Figure 10-9).

Figure 10-9: Inset folded to form a clip

c. Fold the sides of the splash guard inward at the perforations (Figure 10-10).

Figure 10-10: Splash guard folded at the perforations

3 Align the splash guard with the lever assembly on the sealer head.

4 Attach the splash guard and use the clip to lock it in place (Figure 10-11).

Figure 10-11: Attaching the splash guard and locking it in place

5 Reconnect the RF cable, to the sealer head and put the sealer head back into the holder on the Spectra Optia system.

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Seal Safe System Specifications

Table 10-1: Physical

Characteristics	Performance
Physical dimensions (sealer head with RF cable)	Diameter: 2.5 cm (1 in) Relaxed length: Approximately 1.1 m (3.7 ft)
Weight	External parts: 0.4 kg (0.9 lb)

Table 10-2: Environmental

Characteristics	Performance
Ambient operating temperature (sealer head with RF cable)	15 °C to 35 °C (59 °F to 95 °F)
Ambient operating humidity	8% to 90% relative humidity (RH), noncondensing
Cleanability	Unit is not damaged by cleaning with alcohol.
Fluid spillage	Unit is not rendered unsafe by saline spillage on the sealer head and RF cable.
Shipping/storage temperature	0 °C to 60 °C (32 °F to 140 °F)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Glossary of Terms

AC infusion rate — The rate in mL/min/L TBV that anticoagulant is infused to the patient during the run.

ACD-A — An anticoagulant used during apheresis procedures. ACD-A stands for Anticoagulant Citrate Dextrose Solution A.

Albumin — A Plasma protein that helps to maintain fluid balance and to control the viscosity of Plasma.

Allogeneic — In blood transfusion or transplantation, a situation in which the donor and the recipient are different but of the same species.

Alloimmunization — A transfusion complication whereby a recipient develops antibodies toward antigens from a donated blood product.

Anticoagulant (AC) — An agent used to prevent the formation of blood clots.

Antigen — A foreign substance capable of stimulating an immune response when introduced into the body.

Apheresis — A blood component separation procedure in which whole blood is drawn from a patient or donor, and passed through a device that separates the blood into components. Particular components are either removed or collected, and the remaining components are returned.

Autologous — In blood transfusion or transplantation, a situation in which the donor and the recipient are the same.

Bearing — A hard plastic component of the centrifuge loop of the tubing set that connects the loop to the centrifuge arm and to the entrance of the centrifuge loading port.

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Blood component In apheresis, the RBC, WBC, Platelets, and Plasma,

Blood warmer A device used to increase the temperature of fluid or blood delivered or returned to a patient.

Bolus A dose of fluid given to a patient intended to mitigate hypovolemia.

Bone marrow The spongy tissue inside some bones, which contains stem cells.

Buffy coat The fraction of blood after centrifugation that contains most of the white blood cells and platelets.

Cassette A component of the tubing set that snaps onto the front panel of the system and directs the flow of fluid through the set.

Catheter A tube that can be inserted into a vessel, body cavity, or a duct to allow the flow of blood, injection of fluid, or drainage.

Centrifugation A process that uses centrifugal force to separate a mixture.

Centrifuge loop A component of the tubing set. The group of lines that are loaded into the centrifuge.

Channel A component of the tubing set used to separate a patient's blood into cellular components.

Chamber A component of the tubing set used for the secondary separation of platelets and target cells. This component is only on the Collection Set.

Circulatory overload An elevation in blood pressure caused by an increase in blood volume.

Citrate A salt or ester of citric acid, which is used as an anticoagulant because it binds calcium ion.

Citrate toxicity Condition that could occur in certain patients as a result of infusion of ACD-A during an apheresis procedure. Mild forms of this condition are generally recognized by peripheral paresthesia, tingling sensations in the extremities, and/or restlessness. Severe forms of this condition can result in significant cardiac dysfunction.

Clotting The result of activated platelets releasing chemicals that stimulate clotting factors, causing the blood to coagulate.

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Clumping The result of platelets thickening and sticking together during an apheresis procedure.

Collar A six-sided plastic component of the centrifuge loop of the tubing set that secures the end of the loop in the centrifuge.

Collect line A line on the tubing set used to carry collected blood components to the collection bag.

Collection bag A bag on the tubing set that holds collected blood components. This bag is only on the Collection Set.

Connector A component of the tubing set that secures the lines where the separated components exit the channel. It may also facilitate separation.

Custom prime Process of filling the tubing set with specified fluid after priming the set with saline and before starting the run. Useful when treating a patient with a low RBC volume or low TBV to maintain isovolemia.

Default A setting or value that is preset by the manufacturer, and used by the system in the absence of a selection made by the operator.

Diversion bag A bag on the tubing set used to capture a skin plug after performing a peripheral venipuncture, or to collect a blood sample. This bag is only on the Collection Set.

Electrolyte A mineral in blood and body fluids essential to the function of muscle action and other body processes.

Erythrocyte An RBC.

Erythrocytapheresis An apheresis procedure used to separate RBC from a patient's blood.

Electrolyte A mineral in blood and body fluids essential to the function of muscle action and other body processes.

Extracorporeal circuit All of the tubing that carries the blood outside of the patient's body. This includes the Spectra Optia system tubing set and the tubing set of any other device connected to the set.

Extracorporeal volume (ECV) The volume of the patient's blood that is outside of the body during an apheresis procedure.

Four-lumen tubing Lines that comprise the centrifuge loop of the tubing set.

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Fluid shift — A change in the patient's intravascular volume during an apheresis procedure as blood is drawn, one or more components are retained, and the remaining components are returned, with or without replacement fluid.

Fraction of cells remaining (FCR) — The desired percent of starting defective RBC remaining in the patient's blood at the end of a RBC exchange procedure.

Functionally-closed system — A blood collection system that uses sterile barrier filters to prevent bacteria from entering the system.

Gear train — A component of the centrifuge chamber comprised of a series of rotating gears that keep the filler and the centrifuge arm spinning at the proper speed.

Graft-vs.-Host disease — A condition that occurs when cells from a transplanted organ or tissue attack the cells or tissue of the transplant recipient.

Granulocyte — A type of WBC.

Hct — The abbreviation for hematocrit.

Hematoma — A localized collection of blood in an organ, space, or tissue due to a break in the wall of a blood vessel.

Hgb — The abbreviation for hemoglobin.

Hemolysis — A disruption of the RBC membrane, causing the release of hemoglobin.

Hemostat — An instrument used to compress a bleeding vessel or to stop the flow of fluid through a tube.

Inlet:AC ratio — The ratio of the inlet pump flow rate to the AC pump flow rate, expressed as parts of inlet volume to one part of anticoagulant.

Inlet access — Refers to the patient access from which whole blood is drawn.

Inlet flow rate — The speed at which blood is drawn from the patient.

Inlet line — A line on the tubing set used to carry anticoagulated blood from the patient to the channel.

Inlet pressure — The force per unit of area on the blood flow as it is drawn from the patient.

Interface — The common boundary between blood components separated during an apheresis procedure.

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IP (Internet Protocol) address	A numerical identifier for a computer or a device on a network, which enables communication among the devices on the network.
IV	The abbreviation for intravenous.
Leukapheresis	An apheresis procedure used to separate WBC from a patient's blood.
Leukemia	A cancer of the blood-forming cells in the bone marrow.
Lymphocyte	A type of WBC.
Malaria	A disease caused by a parasite and usually transmitted through a mosquito bite, which infects the RBC.
Manifold	A component of the tubing set. Connector with multiple ports used to join a line with one or more other lines. It may also include an injection site.
Manual rinseback	A process whereby the operator performs rinseback, not the system, in case of a power or system failure.
MNC	Abbreviation for Mononuclear Cell or Mononuclear Cells. MNC are a type of WBC.
MNC collection	An apheresis procedure used to collect MNC from a patient.
Obstruction	An object or a condition that restricts the flow of fluid through the tubing set.
Packed RBC	RBC with most of the Plasma removed.
Packing factor	The relationship between the inlet flow rate and the centrifuge speed, which indicates the degree of separation of the blood components during an apheresis procedure.
Paresthesia	A tingling sensation around the mouth, which is a symptom of citrate toxicity or hypocalcemia.
Patient access	Refers to the device used to gain entry to a patient's venous system.
Peripheral blood	The blood in a vein or artery.
Peripheral blood stem cell	A stem cell that circulates in the peripheral blood.
Plasma	The fluid portion of the blood, which transports proteins and enzymes through the body.

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Plasma bag	A bag on the tubing set that holds collected plasma. This bag is only on the Collection Set
Plasma line	A line on the tubing set used to carry concurrently collected Plasma to the Plasma bag. This line is only on the Collection Set.
Plasmapheresis	An apheresis procedure used to separate Plasma from a patient's blood.
Platelet	A small cell fragment that aids in blood coagulation by helping to repair damage to walls of blood vessels.
Port number	A numerical identifier used for the transmission of data between devices in a network.
Prime	The process of pumping saline through the tubing set to prepare the set for the run.
Procedure	The series of steps performed to accomplish apheresis on the Spectra Optia system. A procedure starts when the procedure is selected and ends when the patient is disconnected.
Radio frequency	Any frequency within the range which radio waves are transmitted.
RBC	The abbreviation for Red Blood Cell or Red Blood Cells. RBC carry oxygen to and carbon dioxide from the tissues of the body.
Red Blood Cell depletion	A type of Red Blood Cell Exchange procedure in which excess or defective RBC are removed from a patient, and replaced with desired replacement fluid.
Red Blood Cell depletion/ exchange	A type of Red Blood Cell Exchange procedure that consists of a depletion procedure followed by an exchange procedure.
Red Blood Cell Exchange (RBCX)	An apheresis procedure in which defective RBC are removed from a patient and replaced with healthy donor RBC.
Remove bag	A bag on the tubing set that holds the removed blood components. This bag is only on the Exchange Set.
Remove line	A line on the tubing set used to carry removed blood components from the channel to the remove bag. This line is only on the Exchange Set.

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Replace line	A line on the tubing set used to carry replacement fluid from the replacement fluid container to the reservoir.This line is only on the Exchange Set.
Replacement fluid	The fluid given to the patient during an exchange procedure to replace the blood components removed.
Reservoir	The component of the tubing set cassette that contains the fluid to be returned to the patient.
Reservoir filter	200-micron filter located at the exit of the reservoir used to filter the fluid returned to the patient.
Return access	Refers to the patient access through which blood components and fluids are returned.
Return flow rate	The speed at which blood is returned to the patient.
Return line	The line that carries fluid from the reservoir to the patient.
Return pressure	The force per unit of area on the blood flow as it is drawn from the patient.
Rinseback	The process that clears the channel of remaining cells and returns them to the patient after the run.
Run	The procedure state that starts when the patient is connected and ends when the run targets are attained, during which apheresis is performed.
Saline	A sterile 0.9% sodium chloride and water solution used to prime the tubing set and to perform an apheresis procedure.
Saline rinse	The process that rinses the tubing set with saline before the run to clear the set of any residual ethylene-oxide, a by-product of sterilization.
Sickle cell disease	An inherited blood disorder that affects the hemoglobin in RBC.
Spillover	A term used to indicate that some RBC from the channel have entered the Plasma line.
Stem cell	An unspecialized cell capable of renewing itself through cell division, or of being induced to become a tissue-specific or organ-specific cell.
System reset	The process that occurs when the system restarts itself after a power interruption or under certain alarm conditions.

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Therapeutic apheresis	An apheresis procedure used to remove a pathological blood component in order to treat a patient.
Therapeutic plasma exchange (TPE)	An apheresis procedure in which Plasma is removed from a patient and replaced with new Plasma or a compatible replacement fluid.
Total blood volume (TBV)	The entire volume of the patient's circulating blood, including the Plasma and the cellular components.
Uticaria	A temporary skin condition caused by allergic reaction, and characterized by a rash and severe itching.
Vascular access device	A type of catheter used to access to the central venous system of a patient.
Vent bag	A bag on the tubing set that holds air displaced from the system.
WBC	Abbreviation for White Blood Cell or White Blood Cells. WBC are cells of the immune system that help the body fight infection.

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Essentials Guide

Spectra Optia®

Apheresis System

ESSENTIALS

TERUMOBCT
Unlocking the Potential of Blood

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Attachment 13.3

Instructions for Use
Spectra Optia Exchange Set

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TERUMOBCT

10200, 10220

Spectra Optia® Exchange Set
Instructions for Use
Rx Only

Výměnná souprava Spectra Optia®
Návod k použití
Spectra Optia®-udskiftningssæt
Brugervejledning
Schlauchset für therapeutische Austauschverfahren für das Spectra Optia®-Apheresesystem
Gebrauchsanleitung
Spectra Optia® Σετ ανταλλαγής
Οδηγίες χρήσης
Equipo de recambio Spectra Optia®
Instrucciones de uso
Spectra Optia®-vaihtosarja
Käyttöohjeet
Jeu d'échange Spectra Optia®
Mode d'emploi
Set per scambio terapeutico Spectra Optia®
Istruzioni per l'uso
Spectra Optia 교환 세트
운영 지침
Uitwisselingsset voor het Spectra Optia® systeem
Gebruiksaanwijzing
Utskiftingssett for Spectra Optia®
Bruksanvisning
Zestaw do wymiany Spectra Optia®
Instrukcja obsługi
Conjunto para troca do Spectra Optia
Instruções de uso
Система для плазмафереза к сепаратору Spectra Optia
Инструкция по эксплуатации
Utbytesset för Spectra Optia®
Bruksanvisning
Spectra Optia Değişim Seti
Kullanım Talimatları

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Intended Use

The Spectra Optia® Apheresis System is intended for use in therapeutic apheresis applications. The Spectra Optia® Exchange Set is intended for use with the Spectra Optia® Apheresis System.

Please refer to the Spectra Optia® Apheresis System Operator's Manual for a complete listing of contraindications, adverse effects, warnings, cautions and operating instructions.

Warning

1. Tubing sets manufactured by Terumo BCT contain DEHP. Results from selected studies of rodents exposed to DEHP (typically via an oral route) have shown potentially harmful effects to male reproductive organs during fetal development. Because of this, patient groups that include pregnant or nursing women and children are considered to be most at risk to potential harmful effects of exposure to DEHP. However, no studies performed to date involving other mammals and humans exposed to intravenous DEHP have shown similar results. Regulatory bodies have noted that the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP. It is the responsibility of treating physicians to balance this risk for their patients.

Cautions

1. **Not for Reuse:** Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.
2. The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:
   - Severe kinks in the tubing are apparent.
   - Tubing set appears to be incorrectly assembled.
   - Tubing set is damaged.
   - Any clamps are closed on the lines.
3. You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.
4. Do not stretch the tubing when folding the channel to install it in the centrifuge to avoid damaging the tubing set.
5. Use only your fingers to load the channel into the filler. To avoid puncturing the channel, never use a sharp object.
6. Do not seal the inlet line of the four-lumen tubing. Sealing the line could cause the tubing set to fail when you raise the cassette to unload the set.
7. Ensure all luer connections are secure.
8. Do not use the Exchange Set if the end caps are not in place.
9. Leave the cap on the unused luer (on the remove bag) to prevent fluid leakage. Ensure the cap fits tightly.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Refer to the Spectra Optia® Apheresis System Operator's Manual.

Symbols and Certifications

Symbol	Definition
	Indicates the product quantity when the quantity is placed in the square.
	Indicates the expiration date of the product when accompanied by a specific date.
PYRO	Indicates that the product is non-pyrogenic.
STERILE EO	Indicates a sterile fluid pathway using ethylene oxide (EtO).
	Indicates that the user must read the instructions for use before application.
	Indicates the date of manufacture (or sterilization date, if the product is sterile) when accompanied by a specific date.
REF	Indicates the product catalog number when accompanied by a number.
	Not for Reuse: Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.
Rx Only	Indicates that the use of product is by prescription only.
CE 0086	Device is manufactured in conformance with the European Council Directive 93/42/EEC of June 14, 1993, concerning medical devices. This mark with the Notified Body Number 0086 indicates the approval by the British Standards Institute for these devices within the European Community.
LOT	Indicates the product lot number when accompanied by a number.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definition
	Indicates the manufacturer of the product when accompanied by the name of the manufacturer.
	Indicates that the product must be kept away from sunlight.
	Indicates that the product must be kept dry.
	Indicates that the product packaging complies with European Directive 94/62/EC for packaging and packaging waste.
	Indicates that the product is made from High Density Polyethylene.
	Indicates that the product contains phthalates, specifically Di(2-ethylhexyl)phthalate (DEHP).

Return of Used Product

If for any reason this product must be returned to Terumo BCT, Inc., a returned goods authorization (an RGA number) is required from Terumo BCT prior to shipping.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained from the Terumo BCT Quality Assurance Department.

IT IS THE RESPONSIBILITY OF THE HEALTH CARE INSTITUTION TO ADEQUATELY PREPARE AND IDENTIFY THE PRODUCT FOR RETURN SHIPMENT.

Please contact your local representative for information regarding returned goods and product complaints.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Účel použití

Aferézní systém Spectra Optia® je určený pro použití v terapeutických aferézních aplikacích. Výměnná souprava Spectra Optia® je určená pro použití s aferézním systémem Spectra Optia®.

Přečtěte si příručku pro obsluhu aferézního systému Spectra Optia®, kde jsou uvedeny kompletní údaje o kontraindikacích, nepříznivých účincích, varováních, upozorněních a provozních pokynech.

Varování

1. Sety vyrobené společností Terumo BCT obsahují DEHP. Výsledky vybraných studií na hlodavcích vystavených působení DEHP (obvykle podaným perorálně) prokázaly možné škodlivé účinky DEHP na mužské rozmnožovací orgány během vývoje plodu. Mezi pacienty, u kterých je riziko možného ohrožení vlivem vystavení účinkům DEHP největší, proto patří těhotné a kojící ženy. Žádná ze studií, které byly dosud prováděny na jiných savcích nebo lidech vystavených intravenóznímu podání DEHP, však nic podobného neprokázala. Regulační úřady uvádí, že riziko při neprovedení nutné procedury je mnohem větší než riziko spojené s vystavením účinkům DEHP. Za zvážení tohoto rizika pro pacienta je odpovědný ošetřující lékař.

Upozornění

1. **Není určeno k opakovanému použití:** Sety společnosti Terumo BCT s tímto symbolem jsou určeny pouze k jednorázovému použití a nelze je použít opakovaně. Při opakovaném použití setu nemůže společnost Terumo BCT zajistit jeho funkčnost ani sterilitu.
2. Veškeré části setu, které jsou určené pro průchod krve a tekutin, jsou sterilizovány etylenoxidem a jsou apyrogenní. Nepoužívejte soupravu za následujících podmínek:
   - Na hadičkách je patrné závažné zalomení nebo přehnutí.
   - Souprava je nesprávně sestavena.
   - Souprava je poškozená.
   - Při vybalení soupravy je některá z hadiček uzavřená svorkou.
3. Pokud nezasunete kazetu nebo nenaplníte soupravu, můžete soupravu založit až 24 hodin před procedurou. Jakmile zasunete kazetu nebo naplníte soupravu, musíte soupravu použít během stejné pracovní směny.
4. Při ohýbání separačního prstence před instalací do centrifugy nenatahujte hadičky, abyste je nepoškodili.
5. Při zavádění separačního prstence do náboje používejte pouze prsty. Nikdy nepoužívejte ostré předměty, aby nedošlo k propíchnutí separačního prstence.
6. Nezatavujte čtyřcestnou vstupní linku. Zatavení linky by mohlo způsobit selhání soupravy při vysunování kazety za účelem vyjmutí soupravy.
7. Ujistěte se, že jsou všechna spojení typu Luer pevná.
8. Nepoužívejte výměnnou soupravu, pokud koncové krytky nejsou na svém místě.
9. Na nepoužité koncovce typu luer ponechejte krytku (na odběrovém vaku), abyste zabránili úniku tekutiny. Ujistěte se, že krytka pevně drží.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Používané procedury

Section 3 - 198

Viz příručka operátora aferézního systému Spectra Optia®.

Symboly a osvědčení

Symbol	Definice
	Označuje množství produktu, když je toto množství umístěno ve čtverci.
	Označuje datum trvanlivosti produktu, když je provázen konkrétním datem.
PYRO	Označuje apyrogenní produkt.
STERILE EO	Označuje sterilní dráhu tekutin (sterilizace etylenoxidem).
	Označuje, že si uživatel musí před použitím přečíst návod.
	Označuje datum výroby (nebo datum sterilizace, je-li produkt sterilní), pokud je uvedeno určité datum.
REF	Označuje katalogové číslo produktu, pokud je uvedeno toto číslo.
	Není určeno k opakovanému použití: Sety společnosti Terumo BCT s tímto symbolem jsou určeny pouze k jednorázovému použití a nelze je použít opakovaně. Při opakovaném použití setu nemůže společnost Terumo BCT zajistit jeho funkčnost ani sterilitu.
Rx Only	Označuje, že použití produktu je omezeno na předpis lékaře.
CE 0086	Zařízení je vyrobeno v souladu se směrnicí Evropské rady 93/42/EHS ze 14. června 1993 týkající se lékařských zařízení. Tato značka společně s číslem notifikovaného úřadu 0086 označuje, že toto zařízení bylo schváleno institutem British Standards Institute pro použití v Evropské unii.
LOT	Označuje číslo šarže produktu, pokud je uvedeno toto číslo.
	Označuje výrobce produktu, pokud je uvedeno jméno výrobce.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definice
	Označuje, že produkt nesmí být vystaven slunečnímu záření.
	Označuje, že je produkt nutné udržovat v suchu.
	Označuje, že obal produktu vyhovuje evropské směrnici 94/62/ES o obalech a obalových odpadech.
	Označuje, že je produkt zhotoven z vysokohustotního polyetylenu (HDPE).
	Označuje, že produkt obsahuje ftaláty, konkrétně Di(2-ethylhexyl)ftalát (DEHP).

Vracení použitého produktu

Pokud bude třeba z jakéhokoli důvodu vrátit tento produkt společnosti Terumo BCT, Inc., musíte si před jeho odesláním od společnosti Terumo BCT, Inc. vyžádat povolení pro vrácení zboží (číslo RGA).

Pokyny pro čištění a materiály, včetně vhodných přepravních obalů, správného označení štítky a čísla RGA, si můžete vyžádat od oddělení kontroly kvality společnosti Terumo BCT.

ZDRAVOTNICKÉ ZAŘÍZENÍ JE ZODPOVĚDNÉ ZA ODPOVÍDAJÍCÍ PŘÍPRAVU A IDENTIFIKACI PRODUKTU PRO JEHO ODESLÁNÍ ZPĚT.

Informace o vrácení zboží a reklamaci produktu získáte od vašeho obchodního zástupce.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Tilsigtet brug

Spectra Optia®-aferesesystemet er beregnet til brug ved terapeutiske afereseapplikationer. Spectra Optia®-udskiftningssættet er beregnet til brug med Spectra Optia®-aferesesystemet.

Der henvises til Spectra Optia®-aferesesystemets brugervejledning, hvor der findes en komplet liste over kontraindikationer, bivirkninger, advarsler, forholdsregler og betjeningsinstruktioner.

Advarsel

1. Slangesæt, der er fremstillet af Terumo BCT, indeholder DEHP. Resultater fra udvalgte undersøgelser af gnavere udsat for DEPH (typisk indgivet oralt) har vist potentiel skadelig indvirkning på mandlige reproduktionsorganer under fosterudvikling. Derfor betragtes gravide eller ammende kvinder og børn, som den patientgruppe, der løber den største risiko i forhold til de potentielle skadevirkninger forbundet med eksponering for DEHP. Der er dog ingen undersøgelser udført til dato omfattende andre pattedyr eller mennesker eksponeret for intravenøs DEHP, der har vist lignende resultater. Regulatoriske myndigheder har bemærket, at risikoen ved ikke at udføre et nødvendigt indgreb er langt større end den risiko, der kan være forbundet med eksponering for DEHP. Det er lægernes ansvar at afbalancere denne risiko for deres patienter.

Forsigtighedsregler

1. **Ikke til genbrug:** Slangesæt fremstillet af Terumo BCT, som bærer symbolet 'ikke til genbrug', er beregnet til engangsbrug, og er ikke beregnet til at blive genbearbejdet eller genbrugt. Terumo BCT kan ikke garantere sættets funktion og sterilitet, hvis det genbearbejdes eller genbruges.
2. Blod- og væskebanerne i slangesættet er steriliseret med ethylenoxid, og de er ikke-pyrogene. Sættet må ikke anvendes, hvis et eller flere af følgende forhold er til stede:
   - Der er betydelige knæk på slangerne.
   - Slangesættet synes at være forkert monteret.
   - Slangesættet er beskadiget.
   - En eller flere klemmer er lukket på slangerne.
3. Slangesættet kan isættes op til 24 timer før proceduren, så længe du ikke sænker kassetten eller primer sættet. Når du har sænket kassetten eller primet sættet, skal du bruge sættet i løbet af samme arbejdsdag.
4. For at undgå beskadigelse af slangesættet, må slanger ikke strækkes, når kanalen sammenfoldes ved montering i centrifugen.
5. Brug kun fingrene, når kanalen sættes i filleren. Brug aldrig skarpe genstande for at undgå at perforere kanalen.
6. Forsegl ikke inlet-slangen i fire-lumen-slangesættet. Hvis du forsegler slangen, kan slangesættet svigte, når du løfter kassetten for at fjerne sættet.
7. Sørg for, at alle luer-forbindelser er sikre.
8. Anvend ikke udskiftningssættet, hvis hætterne ikke er på plads.
9. Lad hætten sidde på den ubrugte luer (på opsamlingsposen) for at forhindre væskelækage. Sørg for, at hætten sidder stramt.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Der henvises til Spectra Optia Aferesesystemets® brugervejledning.

Symboler og certificeringer

Symbol	Definition
	Angiver produktmængden, når mængden vises i firkanten.
	Angiver produktets udløbsdato, hvis det ledsages af en specifik dato.
PYRO	Angiver, at produktet er ikke-pyrogent.
STERILE EO	Angiver, at væskebanen er blevet steriliseret med ethylenoxid (EtO).
	Angiver, at operatøren skal læse brugervejledningen før anvendelse.
	Angiver fremstillingsdatoen (eller steriliseringsdatoen, hvis produktet er sterilt), når det ledsages af en specifik dato.
REF	Angiver produktets katalognummer, når det ledsages af et nummer.
	Ikke til genbrug: Slangesæt fremstillet af Terumo BCT, som bærer symbolet 'Ikke til genbrug', er beregnet til engangsbrug, og er ikke beregnet til at blive genbearbejdet eller genbrugt. Terumo BCT kan ikke garantere sættets funktion og sterilitet, hvis det genbearbejdes eller genbruges.
Rx Only	Angiver, at produktet kun må anvendes efter ordinering.
CE 0086	Enheden er fremstillet i overensstemmelse med Rådets direktiv 93/42/EØF fra 14. juni 1993 om medicinsk udstyr. Dette mærke med nummeret 0086 for det bemyndigede organ angiver godkendelse af British Standards Institute af dette udstyr inden for den Europæiske Union.
LOT	Angiver produktets partinummer, når det ledsages af et nummer.
	Angiver producenten af produktet, når det ledsages af navnet på producenten.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definition
	Angiver, at produktet skal holdes væk fra sollys.
	Angiver, at produktet skal opbevares tørt.
	Angiver, at produktemballagen er i overensstemmelse med EU-direktiv 94/62/EF om emballage og emballageaffald.
2 HDPE	Angiver, at produktet er fremstillet af polyethylen med høj densitet.
PHT DEHP	Angiver, at produktet indeholder phthalater, mere specifikt Di(2-ethylhexyl)-phthalat (DEHP).

Returnering af brugt produkt

Hvis produktet af en eller anden årsag skal returneres til Terumo BCT, Inc., er en tilbagesendelsesautorisation (et RGA-nummer) fra Terumo BCT nødvendig inden afsendelse.

Retningslinjer for rengøring og materialer, herunder hensigtsmæssige forsendelsesbeholdere, korrekt etikettering, og et RGA-nummer, kan rekvireres fra Terumo BCT Quality Assurance Department.

DET ER SUNDHEDSINSTITUTIONENS ANSVAR I TILSTRÆKKELIG GRAD AT FORBEREDE OG IDENTIFICERE PRODUKTET TIL TILBAGESENDELSE.

Kontakt din lokale repræsentant for oplysninger om returnerede varer og klager over produkter.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Verwendungszweck

Das Spectra Optia®-Apheresesystem ist zur Anwendung bei therapeutischen Aphereseverfahren konzipiert. Das Spectra Optia®-Schlauchset für therapeutische Austauschverfahren ist für den Gebrauch mit dem Spectra Optia®-Apheresesystem bestimmt.

Eine vollständige Liste der Kontraindikationen, Nebenwirkungen, Warn- und Vorsichtshinweise sowie Anweisungen zu Bedienung finden Sie in der Bedienungsanleitung zum Spectra Optia®-Apharesesystem.

Warnung

1. Von Terumo BCT hergestellte Schlauchsets enthalten DEHP. Ausgewählte Studien an Nagetieren, die DEHP ausgesetzt wurden (typischerweise durch orale Verabreichung), haben potenziell schädliche Auswirkungen auf die männlichen Geschlechtsorgane während der fötalen Entwicklung ergeben. Daher gelten Patientengruppen mit schwangeren oder stillenden Frauen sowie Kindern als am meisten durch die potenziell schädlichen Auswirkungen einer DEHP-Exposition gefährdet. Allerdings haben bislang keine Studien an anderen Säugetieren und Menschen, die intravenösem DEHP ausgesetzt waren, zu ähnlichen Ergebnissen geführt. Aufsichtsbehörden haben festgestellt, dass das Risiko einer Unterlassung eines erforderlichen Verfahrens das Risiko in Verbindung mit einer DEHP-Exposition bei Weitem übersteigt. Die Abwägung dieses Risikos für den Patienten obliegt dem behandelnden Arzt.

Vorsichtshinweise

1. **Einwegprodukt:** Von Terumo BCT hergestellte Schlauchsets, die das Einwegproduktsymbol tragen, sind nur für den einmaligen Gebrauch bestimmt und dürfen nicht wiederaufbereitet oder erneut verwendet werden. Terumo BCT kann die Funktionalität oder Sterilität eines wiederaufbereiteten bzw. erneut verwendeten Sets nicht garantieren.
2. Die Flusswege des Blutes und der Flüssigkeit im Schlauchset sind mit Ethylenoxid sterilisiert und pyrogenfrei. Das Schlauchset nicht benutzen, falls eine oder mehrere der folgenden Bedingungen zutreffen:
   - Die Schläuche sind offensichtlich stark geknickt.
   - Das Schlauchset wurde anscheinend falsch zusammengebaut.
   - Das Schlauchset ist beschädigt.
   - Irgendwo ist ein Schlauch abgeklemmt.
3. Das Schlauchset darf bis zu 24 Stunden vor Beginn eines Verfahrens geladen werden, solange die Kassette nicht abgesenkt und das Schlauchset nicht vorgefüllt wird. Sobald die Kassette abgesenkt oder das Schlauchset vorgefüllt wird, muss das Schlauchset während des gleichen Arbeitsganges verwendet werden.
4. Um eine Beschädigung des Schlauchsets zu vermeiden, die Schläuche nicht dehnen, wenn der Kanal zum Einsetzen in die Zentrifuge gefaltet wird.
5. Kanal nur mit den Fingern in die Füllvorrichtung laden. Niemals einen scharfen Gegenstand verwenden, damit der Kanal nicht durchstochen wird.
6. Den Einlassschlauch des vierlumigen Schlauchsets nicht versiegeln. Andernfalls könnte das Schlauchset lecken, wenn die Kassette zum Entladen des Schlauchsets angehoben wird.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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7. Sicherstellen, dass alle Luer-Anschlüsse fest sitzen.
8. Das Schlauchset für therapeutische Austauschverfahren nicht benutzen, wenn die Verschlusskappen fehlen.
9. Die Kappe des Luer-Anschlusses am zweiten Entzugsschlauch lassen, damit keine Flüssigkeit auslaufen kann. Sicherstellen, dass die Kappe fest sitzt.

Verfahrensanleitung

Siehe Bedienungsanleitung zum Spectra Optia®-Apheresesystem

Symbole und Zertifizierungen

Symbol	Definition
	Gibt die Produktmenge an, wenn eine Stückzahl im Viereck angegeben ist.
	Gibt das Verfallsdatum des Produkts an, wenn ein spezifisches Datum aufgeführt ist.
PYRO	Gibt an, dass das Produkt pyrogenfrei ist.
STERILE EO	Gibt einen sterilen Flüssigkeitsweg mittels Ethylenoxid (EtO) an.
	Gibt an, dass vor der Anwendung die Gebrauchsanleitung zu lesen ist.
	Gibt das Herstelldatum (oder bei einem sterilen Produkt das Sterilisationsdatum) an, wenn ein genaues Datum aufgeführt ist.
REF	Gibt die Bestellnummer des Produkts an, wenn eine Nummer aufgeführt ist.
	Einwegprodukt: Von Terumo BCT hergestellte Schlauchsets, die das Einwegproduktsymbol tragen, sind nur für den einmaligen Gebrauch bestimmt und dürfen nicht wiederaufbereitet oder erneut verwendet werden. Terumo BCT kann die Funktionalität oder Sterilität eines wiederaufbereiteten bzw. erneut verwendeten Sets nicht garantieren.
Rx Only	Gibt an, dass die Verwendung des Produkts verschreibungspflichtig ist.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definition
CE 0086	Das Gerät wird in Übereinstimmung mit der EU-Richtlinie 93/42/EWG für Medizinprodukte (14. Juni 1993) hergestellt. Die Kennzeichnung mit 0086 gibt als Benannte Stelle das British Standards Institute an, das diese Geräte innerhalb der EU genehmigt hat.
LOT	Gibt die Chargennummer des Produkts an, wenn eine Nummer aufgeführt ist.
	Gibt den Hersteller des Produkts an, wenn der Name des Herstellers aufgeführt ist.
	Gibt an, dass das Produkt vor Sonnenlicht geschützt werden muss.
	Gibt an, dass das Produkt trocken gehalten werden muss.
DER GRÜNE PUNKT	Gibt an, dass die Produktverpackung der Richtlinie 94/62/EG für Verpackungen und Verpackungsabfall entspricht.
2 HDPE	Gibt an, dass das Produkt aus hochdichtem Polyethylen besteht.
PHT DEHP	Gibt an, dass das Produkt Phthalate enthält, insbesondere Di(2-ethylhexyl)phthalat (DEHP).

Rücksenden benutzter Produkte

Sollte dieses Produkt aus irgendeinem Grund an Terumo BCT, Inc. zurückgesendet werden müssen, ist vor dem Versand von Terumo BCT eine Produktrücksendegenehmigung (RGA-Nummer) einzuholen.

Hinweise zu Reinigung und Material, einschließlich angemessener Versandverpackung, ordnungsgemäßer Adressierung und Etikettierung und einer RGA-Nummer, können vom Terumo BCT Quality Assurance Department angefordert werden.

BEI EVENTUELLER RÜCKSENDUNG IST DAS BLUTSPENDEZENTRUM FÜR DIE SACHGERECHTE VORBEREITUNG UND KENNZEICHNUNG DES PRODUKTS FÜR DEN VERSAND VERANTWORTLICH.

Hinweise zur Rücksendung von Produkten und zur Einreichung von Produktreklamationen können beim örtlichen Vertreter eingeholt werden.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Προοριζόμενη χρήση

Το σύστημα αφαίρεσης Spectra Optia® προορίζεται για χρήση σε εφαρμογές θεραπευτικής αφαίρεσης. Το σετ ανταλλαγής Spectra Optia® προορίζεται για χρήση με το σύστημα αφαίρεσης Spectra Optia®.

Ανατρέξτε στο εγχειρίδιο χειριστή του συστήματος αφαίρεσης Spectra Optia® για έναν πλήρη κατάλογο των αντενδείξεων, των ανεπιθύμητων ενεργειών, των προειδοποιήσεων, των συστάσεων προσοχής και των οδηγιών λειτουργίας.

Προειδοποίηση

1. Τα σετ σωλήνων που κατασκευάζονται από την Terumo BCT περιέχουν DEHP. Σύμφωνα με αποτελέσματα από επιλεγμένες μελέτες σε τρωκτικά που εκτέθηκαν σε DEHP (κατά κανόνα διά της στοματικής οδού), υπάρχουν δυνάμει επιβλαβείς συνέπειες για τα ανδρικά αναπαραγωγικά όργανα κατά την εμβρυϊκή ανάπτυξη. Ως εκ τούτου, οι ομάδες ασθενών που περιλαμβάνουν γυναίκες σε περίοδο κύησης ή γαλουχίας και θηλάζοντα παιδιά θεωρείται ότι διατρέχουν τον μεγαλύτερο κίνδυνο από τις επιβλαβείς συνέπειες της έκθεσης στο DEHP. Ωστόσο, καμία από τις μελέτες που έχουν διενεργηθεί μέχρι σήμερα σε άλλα θηλαστικά και σε ανθρώπους που εκτέθηκαν ενδοφλεβίως σε DEHP δεν έχει καταδείξει παρόμοια αποτελέσματα. Διάφορες ρυθμιστικές αρχές έχουν επισημάνει τον κίνδυνο παράλειψης μιας αναγκαίας ιατρικής επέμβασης ως πολύ μεγαλύτερο από τον κίνδυνο που σχετίζεται με την έκθεση στην ουσία DEHP. Αποτελεί ευθύνη των θεράποντων ιατρών να σταθμίζουν τον εν λόγω κίνδυνο έναντι του οφέλους για τους ασθενείς τους.

Συστάσεις προσοχής

1. **Μην επαναχρησιμοποιείτε:** Τα σετ σωλήνων που κατασκευάζονται από την Terumo BCT και φέρουν το σύμβολο μη επαναχρησιμοποίησης προορίζονται για μία χρήση μόνο και δεν πρέπει να επαναχρησιμοποιούνται ή να υποβάλλονται σε εκ νέου επεξεργασία. Η Terumo BCT δεν μπορεί να εγγυηθεί τη λειτουργική ακεραιότητα ή τη στειρότητα του σετ εάν αυτό επαναχρησιμοποιηθεί ή υποβληθεί σε εκ νέου επεξεργασία.
2. Οι οδοί αίματος και υγρών των σετ σωλήνων έχουν αποστειρωθεί με αιθυλενοξείδιο και δεν είναι πυρετογόνοι. Μη χρησιμοποιείτε το σετ εάν ισχύει οποιαδήποτε από τις παρακάτω συνθήκες:
   - Εάν οι σωλήνες είναι πολύ συνεστραμμένοι.
   - Εάν το σετ σωλήνων φαίνεται να μην έχει συναρμολογηθεί σωστά.
   - Εάν το σετ σωλήνων εμφανίζει ίχνη ζημιάς.
   - Εάν είναι κλεισμένος οποιοσδήποτε σφιγκτήρας γραμμής.
3. Μπορείτε να φορτώσετε το σετ σωλήνων έως και 24 ώρες πριν από την εκτέλεση του πρωτοκόλλου, υπό την προϋπόθεση ότι δεν θα χαμηλώσετε την κασέτα και δεν θα προχωρήσετε σε προπλήρωση του σετ. Μετά το χαμήλωμα της κασέτας ή την προπλήρωση του σετ, το σετ πρέπει να χρησιμοποιείται εντός της ίδιας βάρδιας εργασίας.
4. Μην τεντώνετε τους σωλήνες όταν διπλώνετε τη στεφάνη για να την τοποθετήσετε στη φυγόκεντρο. Διαφορετικά μπορεί να προκληθεί ζημιά στο σετ σωλήνων.
5. Χρησιμοποιείτε μόνο τα δάχτυλά σας για να φορτώσετε τη στεφάνη στον αγωγό. Για την αποφυγή του κινδύνου διάτρησης της στεφάνης, μη χρησιμοποιείτε ποτέ αιχμηρά αντικείμενα.

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6. Μη συσφίξετε τη γραμμή τροφής των σωλήνων τεσσάρων αυλών. Αν συσφίξετε τη γραμμή, μπορεί να προκληθεί αστοχία του σετ σωλήνων όταν ανεβάσετε την κασέτα για να εκφορτώσετε το σετ.
7. Βεβαιωθείτε ότι έχουν συνδεθεί με ασφάλεια όλες οι συνδέσεις luer.
8. Μη χρησιμοποιείτε το σετ ανταλλαγής εάν απουσιάζουν τα πώματα των άκρων.
9. Για την αποτροπή του κινδύνου διαρροής υγρού, αφήνετε το πώμα επάνω στον μη χρησιμοποιημένο σύνδεσμο luer (στον ασκό αφαίρεσης). Βεβαιωθείτε ότι το πώμα σφραγίζει εντελώς.

Διαδικασίες χρήσης

Ανατρέξτε στο εγχειρίδιο χειριστή του συστήματος αφαίρεσης Spectra Optia®.

Σύμβολα και πιστοποιήσεις

Σύμβολο	Ορισμός
	Υποδεικνύει την ποσότητα του προϊόντος όταν η ποσότητα τοποθετείται στο τετράγωνο.
	Υποδεικνύει την ημερομηνία λήξης του προϊόντος όταν συνοδεύεται από συγκεκριμένη ημερομηνία.
PYRO	Υποδεικνύει ότι το προϊόν είναι μη πυρετογόνο.
STERILE EO	Υποδεικνύει μια στείρα οδό υγρών με χρήση αιθυλενοξειδίου (EtO).
	Υποδεικνύει ότι ο χρήστης πρέπει να διαβάσει τις οδηγίες χρήσης πριν από την εφαρμογή.
	Υποδεικνύει την ημερομηνία κατασκευής (ή ημερομηνία αποστείρωσης αν το παράγωγο είναι στείρο) όταν συνοδεύεται από συγκεκριμένη ημερομηνία.
REF	Υποδηλώνει τον αριθμό καταλόγου του προϊόντος όταν συνοδεύεται από αριθμό.
	Μην επαναχρησιμοποιείτε: Τα σετ σωλήνων που κατασκευάζονται από την Terumo BCT και φέρουν το σύμβολο μη επαναχρησιμοποίησης προορίζονται για μία χρήση μόνο και δεν πρέπει να επαναχρησιμοποιούνται ή να υποβάλλονται σε εκ νέου επεξεργασία. Η Terumo BCT δεν μπορεί να εγγυηθεί τη λειτουργική ακεραιότητα ή τη στειρότητα του σετ αν αυτό επαναχρησιμοποιηθεί ή υποβληθεί σε εκ νέου επεξεργασία.

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Σύμβολο	Ορισμός
Rx Only	Υποδεικνύει ότι η χρήση του προϊόντος γίνεται αποκλειστικά κατόπιν ιατρικής συνταγής.
CE 0086	Η συσκευή κατασκευάζεται σύμφωνα με την Οδηγία του Ευρωπαϊκού Συμβουλίου 93/42/ΕΟΚ με ημερομηνία 14 Ιουνίου 1993, που αφορά τα ιατροτεχνολογικά προϊόντα. Η σήμανση αυτή φέρει τον Αριθμό κοινοποιημένου φορέα 0086 που δηλώνει την έγκριση από το Βρετανικό Ινστιτούτο Προτύπων αυτών των συσκευών εντός της Ευρωπαϊκής Κοινότητας.
LOT	Υποδηλώνει τον αριθμό παρτίδας του προϊόντος όταν συνοδεύεται από αριθμό.
	Υποδεικνύει την ημερομηνία κατασκευής του προϊόντος όταν συνοδεύεται από την επωνυμία του κατασκευαστή.
	Υποδεικνύει ότι το προϊόν πρέπει να φυλάσσεται μακριά από το ηλιακό φως.
	Υποδεικνύει ότι το προϊόν πρέπει να διατηρείται στεγνό.
DER GRÜNE PUNKT	Υποδεικνύει ότι η συσκευασία του προϊόντος είναι σύμφωνη με την Ευρωπαϊκή οδηγία 94/62/ΕΚ σχετικά με τις συσκευασίες και τα απορρίμματα συσκευασίας.
2 HDPE	Υποδεικνύει ότι το προϊόν είναι παρασκευασμένο από πολυαιθυλένιο υψηλής πυκνότητας
PHT DEHP	Υποδεικνύει ότι το προϊόν περιέχει φθαλικά και συγκεκριμένα Φθαλικό δι-(2-αιθυλοεξυλο) εστέρα (DEHP).

Επιστροφή του χρησιμοποιημένου προϊόντος

Εάν το προϊόν αυτό πρέπει να επιστραφεί για οποιονδήποτε λόγο στην Terumo BCT, Inc., τότε απαιτείται η λήψη εξουσιοδότησης επιστρεφόμενου είδους (κωδικός RGA) από την Terumo BCT πριν από την αποστολή.

Οδηγίες καθαρισμού και υλικά, στα οποία συμπεριλαμβάνονται τα κατάλληλα δοχεία αποστολής, η σωστή επισήμανση και ο κωδικός RGA, μπορούν να αποκτηθούν από το τμήμα διασφάλισης ποιότητας της Terumo BCT.

Η ΚΑΤΑΛΛΗΛΗ ΠΡΟΕΤΟΙΜΑΣΙΑ ΚΑΙ Η ΤΑΥΤΟΠΟΙΗΣΗ ΤΟΥ ΕΠΙΣΤΡΕΦΟΜΕΝΟΥ ΠΡΟΪΟΝΤΟΣ ΑΠΟΤΕΛΟΥΝ ΕΥΘΥΝΗ ΤΟΥ ΝΟΣΗΛΕΥΤΙΚΟΥ ΙΔΡΥΜΑΤΟΣ.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Επικοινωνήστε με τον τοπικό αντιπρόσωπο προκειμένου να λάβετε πληροφορίες για τα επιστρεφόμενα είδη και για την υποβολή παραπόνων σχετικά με τα προϊόντα.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Uso específico

El sistema de aféresis Spectra Optia® se ha diseñado para su uso en aplicaciones de aféresis terapéutica. El equipo de recambio de Spectra Optia® está diseñado para utilizarse con el sistema de aféresis Spectra Optia®.

Consulte el Manual del usuario del sistema de aféresis Spectra Optia® para ver un listado completo de contraindicaciones, efectos adversos, advertencias, precauciones e instrucciones de funcionamiento.

Advertencia

1. Los equipos de líneas fabricados por Terumo BCT contienen DEHP. Los resultados obtenidos en un conjunto seleccionado de estudios sobre roedores expuestos al DEHP (normalmente por vía oral) muestran posibles efectos dañinos en el aparato reproductor masculino durante el desarrollo del feto. Por esta razón, se considera que los grupos de pacientes que incluyen a mujeres embarazadas o lactantes y niños son los que tienen mayor riesgo de padecer los posibles efectos negativos de la exposición al DEHP. Sin embargo, ningún estudio de los realizados hasta la fecha con otros mamíferos y humanos expuestos al DEHP por vía intravenosa ha dado resultados similares. Los organismos reguladores han observado que el riesgo de no realizar un procedimiento necesario es mucho mayor que el riesgo asociado con la exposición al DEHP. Es responsabilidad del médico valorar este riesgo en el caso de sus pacientes.

Precauciones

1. **No reutilizar:** los equipos de líneas fabricados por Terumo BCT que llevan el símbolo de no reutilizar están indicados para un solo uso y no se deben reprocesar ni reutilizar. Terumo BCT no puede garantizar la funcionalidad ni la esterilidad del equipo de líneas si este se reprocesa o se reutiliza.
2. Los recorridos de la sangre y del líquido en el sistema de líneas han sido esterilizados con óxido de etileno y son apirógenos. No utilice el equipo en ninguna de las siguientes condiciones:
   - Las líneas muestran graves acodamientos.
   - Parece que el equipo de líneas no está correctamente montado.
   - El equipo de líneas está dañado.
   - Las líneas tienen alguna pinza cerrada.
3. Puede cargar el equipo de líneas hasta 24 horas antes del procedimiento, siempre que no descienda el casete ni cebe el equipo. Cuando baje el casete o cebe el equipo, deberá utilizar el equipo durante el mismo turno de trabajo.
4. No estire las líneas cuando doble el canal para su instalación en la centrífuga a fin de evitar dañar el equipo de líneas.
5. Utilice únicamente los dedos para colocar el canal en el plato de separación. Para evitar que se dañe el canal no use nunca objetos afilados.
6. No selle la línea de entrada de las líneas de cuatro luces. Si se sella, el equipo de líneas podría fallar al levantar el casete para retirar el equipo.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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7. Asegúrese de que todos los conectores luer estén apretados.

8. No utilice el equipo de recambio terapéutico si los protectores de los punzones no están colocados correctamente.

9. Deje el protector de punzones en la jeringa luer no utilizada (en la bolsa de extracción) para evitar que se escapen fluidos. Asegúrese de que el protector se ajuste correctamente.

Procedimientos de uso

Consulte el Manual de funcionamiento del sistema de aféresis Spectra Optia®.

Símbolos y certificaciones

Símbolo	Definición
	Indica la cantidad del producto cuando la cantidad se detalla en el cuadro.
	Indica la fecha de caducidad del producto cuando se acompaña de una fecha determinada.
PYRO	Indica que el producto es apirógeno.
STERILE EO	Indica un conducto de fluidos que se ha esterilizado con óxido de etileno (OEt).
	Indica que el usuario debe leer las instrucciones de uso del producto antes de su aplicación.
	Indica la fecha de fabricación (o la fecha de esterilización, si el producto es estéril) cuando se acompaña de una fecha específica.
REF	Indica el número de catálogo del producto cuando se acompaña de un número.
	No reutilizar: los equipos de líneas fabricados por Terumo BCT que llevan el símbolo de no reutilizar están indicados para un solo uso y no se deben reprocesar ni reutilizar. Terumo BCT no puede garantizar la funcionalidad ni la esterilidad del equipo de líneas si este se reprocesa o se reutiliza.
Rx Only	Indica que el producto debe utilizarse únicamente bajo prescripción médica.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Símbolo	Definición
CE 0086	El dispositivo se fabrica según la directiva 93/42/CEE del Consejo Europeo, del 14 de junio de 1993, relativa a los dispositivos médicos. Esta marca tiene el número 0086 de organismo notificado, que indica la aprobación de estos dispositivos dentro de la Comunidad Europea por parte de British Standards Institute.
LOT	Indica el número de lote del producto cuando se acompaña de un número.
	Indica el fabricante del producto cuando se acompaña del nombre del fabricante.
	Indica que el producto debe protegerse de la luz solar.
	Indica que el producto debe mantenerse seco.
DER GRÜNE PUNKT	Indica que el envasado del producto cumple la Directiva Europea 94/62/CE sobre envases y residuos de envases.
2 HDPE	Indica que el producto está fabricado con polietileno de alta densidad.
PHT DEHP	Indica que el producto contiene ftalatos, específicamente ftalato de di(2-etilhexilo) (DEHP).

Devolución de productos usados

Si, por cualquier razón, este producto debe devolverse a Terumo BCT, Inc., es necesario contar con la autorización previa de devolución de mercancías (un número RGA) de Terumo BCT antes del envío.

Las instrucciones de limpieza y los materiales, incluidos los contenedores de envío adecuados, el etiquetado correcto y el número de RGA pueden obtenerse del departamento de calidad de Terumo BCT.

LA RESPONSABILIDAD DE PREPARAR E IDENTIFICAR ADECUADAMENTE EL PRODUCTO PARA SU DEVOLUCIÓN RECAE EXCLUSIVAMENTE EN LA INSTITUCIÓN SANITARIA.

Póngase en contacto con su representante local para obtener información acerca de la devolución de productos y la presentación de quejas.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Käyttötarkoitus

Spectra Optia® -afereesijärjestelmä on tarkoitettu käyttöön terapeuttisissa afereesihoidoissa. Spectra Optia® -vaihtosarja on tarkoitettu käyttöön ® Spectra Optia -afereesijärjestelmän kanssa.

Katso kattava kontraindikaatioiden, haittavaikutusten, varoitusten, muistutusten ja käyttöohjeiden luettelo Spectra Optia® -afereesijärjestelmän käyttöoppaasta.

Varoitus

1. Terumo BCT:n valmistamat letkusarjat sisältävät DEHP:tä. Tulokset valikoiduista tutkimuksista, joissa jyrsijöitä altistettiin DEHP:lle (tyypillisesti suun kautta), ovat osoittaneet mahdollisesti haitallisia vaikutuksia urosten lisääntymiselimille sikiön kehityksen aikana. Tästä syystä potilasryhmien, joissa on raskaana olevia tai imettäviä naisia ja lapsia, katsotaan olevan suurimmassa vaarassa saada mahdollisia haittavaikutuksia DEHP-altistuksesta. Tähän mennessä tehdyt tutkimukset, jotka on tehty laskimonsisäiselle DEHP:lle altistuneille muille nisäkkäille ja ihmisille, eivät kuitenkaan ole osoittaneet samankaltaisia tuloksia. Valvontaviranomaiset ovat huomauttaneet, että tarvittavan toimenpiteen tekemättä jättämisen riski on paljon suurempi kuin DEHP-altistukseen liittyvä riski. On hoitavien lääkärien vastuulla punnita tämä riski omien potilaidensa kohdalla.

Muistutukset

1. **Ei saa käyttää uudelleen:** Terumo BCT:n valmistamat letkusarjat, joissa on uudelleenkäytön kieltävä symboli, on tarkoitettu kertakäyttöisiksi eikä niitä saa käsitellä tai käyttää uudelleen. Terumo BCT ei voi taata uudelleen käsitellyn tai käytetyn sarjan toimivuutta tai steriiliyttä.
2. Letkusarjan veri- ja nestereitit on steriloitu eteenioksidilla, ja ne ovat pyrogeenittomia. Älä käytä sarjaa, jos mikä tahansa seuraavista tilanteista ilmenee:
   - Letkuissa on jyrkkiä mutkia.
   - Letkusarja näyttää väärin kootulta.
   - Letkusarja on vahingoittunut.
   - Mikä tahansa linjoilla oleva letkun suljin on suljettu.
3. Letkusarja voidaan ladata enintään 24 tuntia ennen toimenpidettä, kunhan kasettia ei lasketa eikä sarjaa esitäytetä. Kun kasetti on asetettu alas tai sarja esitäytetty, sarjaa on käytettävä saman työvuoron aikana.
4. Älä venytä letkua, kun kanava laitetaan sentrifugiin asennusta varten, jotta letkusarja ei vahingoitu.
5. Lataa kanava kiinnityskappaleeseen käyttäen vain sormia. Älä käytä teräviä esineitä, jotta kanava ei puhkea.
6. Älä sinetöi nelikanavaisten letkujen imuletkua. Jos letku sinetöidään, letkusarja ei ehkä toimi, kun kasetti nostetaan sarjan poistamista varten.
7. Varmista, että kaikki luer-liitännät ovat kunnolla kiinni.
8. Älä käytä vaihtosarjaa, jos suojakorkit eivät ole paikoillaan.
9. Jätä korkki käyttämättömään luer-liittimeen (poistopussissa), jotta neste ei pääse vuotamaan. Varmista, että korkki on kunnolla kiinni.

estions? Contact FDA/CDRH/OGE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Katso Spectra Optia® -afereesijärjestelmän käyttöopasta.

Symbolit ja sertifikaatit

Symboli	Määritelmä
	Tuotteen määrä, kun määrä on merkitty neliön sisään.
	Tuotteen viimeinen käyttöpäivämäärä, kun päivämäärä on näkyvissä.
PYRO	Pyrogeeniton tuote.
STERILE EO	Nestereitti on steriloitu eteenioksidilla (EtO).
	Käyttäjän tulee lukea käyttöohjeet ennen käyttöä.
	Valmistuspäivämäärä (tai sterilointipäivämäärä, jos tuote on steriili), kun tarkka päivämäärä on näkyvissä.
REF	Tuotteen luettelonumero, kun numero näkyvissä.
	Ei saa käyttää uudelleen: Terumo BCT:n valmistamat letkusarjat, joissa on uudelleenkäytön kieltävä symboli, on tarkoitettu kertakäyttöisiksi eikä niitä saa käsitellä tai käyttää uudelleen. Terumo BCT ei voi taata uudelleen käsitellyn tai käytetyn sarjan toimivuutta tai steriiliyttä.
Rx Only	Tuotteen käyttöön vaaditaan lääkärin määräys.
CE 0086	Laite on valmistettu 14. kesäkuuta 1993 annetun, lääkinnällisiä laitteita koskevan Euroopan neuvoston direktiivin 93/42/ETY mukaisesti. Tämä merkki, jossa on ilmoitetun tarkastuslaitoksen numero 0086, osoittaa British Standards Instituten näille laitteille Euroopan yhteisössä antaman hyväksynnän.
LOT	Tuotteen eränumero, kun numero on näkyvissä.
	Tuotteen valmistaja, kun valmistajan nimi on näkyvissä.

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Symboli	Määritelmä
	Tuote on pidettävä poissa auringonvalosta.
	Tuote on pidettävä kuivana.
	Tuotteen pakkaus noudattaa Euroopan pakkaus- ja pakkausjätedirektiiviä 94/62/EY.
	Tuote on tehty suuritiheyksisestä polyeteenistä.
	Tuote sisältää ftalaatteja, erityisesti di(2-etyyliheksyyli)ftalaattia (DEHP:tä).

Käytetyn tuotteen palautus

Jos tämä tuote on jostain syystä palautettava Terumo BCT, Inc:lle, ennen lähettämistä on Terumo BCT:ltä saatava tavaranpalautuslupa (RGA-numero).

Puhdistusohjeet ja materiaalit, mukaan lukien asianmukaiset lähetyspakkaukset, pakkausmerkinnät ja RGA-numero, ovat saatavissa Terumo BCT:n laadunvarmistusosastolta.

TUOTTEEN PALAUTUSLÄHETYKSEN ASIANMUKAINEN PAKKAAMINEN JA MERKITSEMINEN ON LÄHETTÄVÄN HOITOLAITOKSEN VASTUULLA.

Palautettuihin tavaroihin ja reklamaatioihin liittyviä tietoja saa ottamalla yhteyden yhtiön paikalliseen edustajaan.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Utilisation prévue

Le système d'aphérèse Spectra Optia® est destiné aux applications d'aphérèse thérapeutique. Le kit d'échange Spectra Optia® est conçu pour être utilisé avec le système d'aphérèse Spectra Optia®.

Consultez le manuel d'utilisation du système d'aphérèse Spectra Optia® pour une liste complète des contre-indications, effets indésirables, avertissements, mises en garde et instructions d'utilisation.

Avertissement

1. Les kits de tubulures fabriqués par Terumo BCT contiennent du DEHP. Les résultats de certaines études portant sur des rongeurs exposés au DEHP (généralement par voie orale) ont démontré un effet potentiellement délétère sur les organes reproducteurs mâles pendant le développement fœtal. Par conséquent, les groupes de patients comprenant des enfants et des femmes enceintes ou qui allaitent sont considérés comme particulièrement vulnérables aux risques potentiels liés à l'exposition au DEHP. Toutefois, aucune des études réalisées à ce jour sur d'autres mammifères et sur des êtres humains exposés au DEHP par voie intraveineuse n'a présenté de résultats similaires. Des organismes de réglementation ont indiqué que le risque lié à la non-réalisation d'une procédure nécessaire était nettement supérieur au risque lié à l'exposition au DEHP. Il revient au médecin traitant d'évaluer ces différents risques pour ses patients.

Mises en garde

1. **À usage unique :** les kits de collecte fabriqués par Terumo BCT portant le symbole d'usage unique ne doivent être utilisés qu'une seule fois et ne peuvent pas être reconditionnés ni réutilisés. Terumo BCT ne peut garantir la fonctionnalité ou la stérilité du kit en cas de reconditionnement ou de réutilisation.
2. Les voies de passage du sang et des liquides du kit de tubulures sont apyrogènes et stérilisées à l’oxyde d’éthylène.Ne pas utiliser le kit dans les cas suivants :
   - Les tubes présentent des coudes prononcés.
   - Le kit n'est pas assemblé correctement.
   - Le kit est endommagé.
   - Des clamps sont fermés sur les tubulures.
3. Vous pouvez charger le kit 24 heures avant la procédure tant que vous n'abaissez pas la cassette ou n'amorcez pas le kit. Une fois la cassette abaissée ou le kit amorcé, vous devez utiliser le kit dans la journée.
4. Pour éviter d'endommager le kit de tubulures, ne pas étirer la tubulure lors du pliage de l'anneau de centrifugation qui va être placé dans la centrifugeuse.
5. Veillez à charger l’anneau dans le plateau uniquement avec les doigts. Pour éviter une perforation accidentelle de l’anneau de centrifugation, ne jamais utiliser d'objet pointu.
6. Ne soudez pas la tubulure de prélèvement de la tubulure à quatre faisceaux. Souder la tubulure peut entraîner une défaillance du kit lors de l'élévation de la cassette au moment du déchargement du kit.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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7. Vérifiez que tous les raccords Luer sont bien fermés.
8. N'utilisez pas le jeu d'échange si les capuchons de protection ne sont pas en place.
9. Laissez le capuchon sur la connexion Luer inutilisée (sur la poche d'extraction) pour éviter les fuites de fluide. Vérifiez que le bouchon est bien ajusté.

Procédures d'utilisation

Se reporter au manuel d'utilisation du système d'aphérèse Spectra Optia®.

Symboles et homologations

Symbole	Définition
	Indique la quantité du produit lorsqu'elle est mentionnée dans le carré.
	Indique la date de péremption du produit lorsqu'il est accompagné d'une date spécifique.
PYRO	Indique que le produit est apyrogène.
STERILE EO	Indique que le trajet des liquides est stérilisé à l'oxyde d'éthylène (EtO).
	Indique que l'utilisateur doit lire le mode d'emploi avant toute application.
	Indique la date de fabrication (ou de stérilisation, si le produit est stérile), lorsqu'il est accompagné d'une date spécifique.
REF	Indique le numéro de catalogue du produit lorsqu'il est accompagné d'un numéro.
	À usage unique : les kits de collecte fabriqués par Terumo BCT portant le symbole d'usage unique ne doivent être utilisés qu'une seule fois et ne peuvent pas être reconditionnés ni réutilisés. Terumo BCT ne peut garantir la fonctionnalité ou la stérilité du kit en cas de reconditionnement ou de réutilisation.
Rx Only	Indique que l'utilisation du produit est uniquement sur ordonnance.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbole	Définition
CE 0086	L'appareil est fabriqué conformément à la Directive 93/42/CEE du Conseil du 14 juin 1993 relative aux dispositifs médicaux. Cette marque porte le numéro d'Organisme notifié 0086, indiquant l'approbation du British Standards Institute pour ces appareils au sein de l'Union européenne.
LOT	Indique le numéro de lot du produit lorsqu'il est accompagné d'un numéro.
	Indique le fabricant du produit lorsqu'il est accompagné du nom du fabricant.
	Indique que le produit doit être conservé à l'abri du soleil.
	Indique que le produit doit être conservé au sec.
DER GRÜNE PUNKT	Indique que l'emballage du produit est conforme à la Directive européenne 94/62/CE relative aux emballages et aux déchets d'emballages.
2 HDPE	Indique que le produit est fabriqué en polyéthylène haute densité.
PHT DEHP	Indique que le produit contient des phtalates, plus spécifiquement du phtalate de Di(2-éthylhexyle) (DEHP).

Renvoi des produits usagés

Si ce produit doit être renvoyé à Terumo BCT, Inc. pour une raison quelconque, il convient d'obtenir un numéro d'autorisation de renvoi de marchandise (numéro RGA) auprès de Terumo BCT avant de procéder à l'expédition.

Les instructions de nettoyage et le matériel, y compris les emballages et étiquettes appropriés, et un numéro RGA peuvent être obtenus auprès du service de contrôle qualité de Terumo BCT.

IL INCOMBE À L'ÉTABLISSEMENT DE SANTÉ DE PRÉPARER ET D'IDENTIFIER CORRECTEMENT LE PRODUIT AVANT DE LE RENVOYER.

Contacter le représentant local pour obtenir des informations concernant les marchandises renvoyées et les réclamations sur les produits.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Uso previsto

Il sistema di aferesi Spectra Optia® viene utilizzato in applicazioni di aferesi terapeutica. Il set per scambio terapeutico Spectra Optia® è destinato all'uso con il sistema di aferesi Spectra Optia®.

Per l'elenco completo delle controindicazioni, degli effetti indesiderati, delle avvertenze, degli avvisi e delle istruzioni operative, fare riferimento al Manuale d'istruzione del sistema di aferesi Spectra Optia®.

Avviso

1. I circuiti fabbricati da Terumo BCT contengono DEHP. I risultati di studi selezionati su roditori esposti a DEHP (generalmente per via orale) hanno mostrato effetti potenzialmente dannosi sull'apparato riproduttivo maschile durante lo sviluppo fetale. Per questo motivo, i gruppi di pazienti che includono donne incinte o in allattamento e bambini sono considerati più a rischio di potenziali effetti nocivi dell'esposizione a DEHP. Tuttavia, nessuno studio eseguito finora su altri mammiferi o esseri umani esposti a DEHP per via endovenosa ha mostrato risultati analoghi. Gli enti normativi hanno osservato che il rischio insito nella mancata esecuzione di una procedura necessaria è molto superiore al rischio associato all'esposizione al DEHP. La valutazione dei rischi sui pazienti è responsabilità del medico curante.

Avvertenze

1. **Non riutilizzare:** i circuiti prodotti da Terumo BCT recanti il simbolo "non riutilizzare" sono strettamente monouso e non vanno ricondizionati o riutilizzati. Terumo BCT non può garantire la funzionalità o la sterilità dei circuiti ricondizionati o riutilizzati.
2. I percorsi del sangue e dei liquidi nel circuito sono sterilizzati con ossido di etilene e sono apirogeni. Non utilizzare il circuito in nessuna delle seguenti circostanze:
   - I tubi presentano attorcigliature evidenti;
   - Il circuito pare assemblato incorrettamente;
   - Il circuito è danneggiato.
   - Morsetti chiusi sulle linee.
3. Il circuito può essere caricato al massimo 24 ore prima della procedura, purché non venga abbassata la cassetta e non venga eseguito il priming del circuito. Una volta abbassata la cassetta o eseguito il priming del circuito, il circuito deve essere utilizzato entro la fine del turno di lavoro.
4. Non tirare i tubi durante la piegatura della cintura per l’installazione nella centrifuga in modo da evitare di danneggiare il circuito.
5. Servirsi solo delle dita per caricare la cintura nel piatto. Per evitare di perforare la cintura, non utilizzare mai oggetti appuntiti.
6. Non saldare la linea di ingresso dei tubi quadrilume. La saldatura della linea potrebbe causare un malfunzionamento del circuito quando si solleva la cassetta per scaricare il circuito.

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7. Verificare che tutti i connettori luer siano saldamente fissati.
8. Non utilizzare il set per scambio terapeutico se i cappucci terminali non sono nella posizione prevista.
9. Lasciare il cappuccio sul connettore luer non utilizzato (sulla sacca di rimozione) per evitare la fuoriuscita di liquido. Verificare che il cappuccio sia fissato saldamente.

Procedure per l'uso

Fare riferimento al Manuale d'istruzione del sistema di aferesi Spectra Optia®.

Simboli e certificazioni

Simbolo	Definizione
	Se nel riquadro è inserita una quantità, indica la quantità del prodotto.
	Se accompagnato da una data specifica, indica la data di scadenza del prodotto.
PYRO	Indica che il prodotto è apirogeno.
STERILE EO	Indica un percorso del liquido reso sterile con ossido di etilene (EtO).
	Indica che l'utente deve leggere le istruzioni per l'uso prima dell'applicazione.
	Se accompagnato da una data specifica, indica la data di produzione (o la data di sterilizzazione, se il prodotto è sterile).
REF	Se accompagnato da un numero, indica il numero di catalogo del prodotto.
	Non riutilizzare: i circuiti prodotti da Terumo BCT recanti il simbolo "non riutilizzare" sono strettamente monouso e non vanno ricondizionati o riutilizzati. Terumo BCT non può garantire la funzionalità o la sterilità dei circuiti ricondizionati o riutilizzati.
Rx Only	Indica che il prodotto può essere utilizzato solo su prescrizione medica.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Simbolo	Definizione
CE 0086	Il dispositivo è prodotto in conformità con la Direttiva europea 93/42/CE del 14 giugno 1993, relativa ai dispositivi medicali. Questo simbolo con il Numero di Organismo Notificato 0086 indica l'approvazione di questi dispositivi da parte del British Standards Institute della Comunità Europea.
LOT	Se accompagnato da un numero, indica il numero di lotto del prodotto.
	Se accompagnato da un nome, indica il fabbricante del prodotto.
	Indica che il prodotto deve essere tenuto al riparo dalla luce solare.
	Indica che il prodotto deve essere tenuto al riparo dall'umidità.
DER GRÜNE PUNKT	Indica che la confezione del prodotto è conforme alla Direttiva europea 94/62/CE riguardante gli imballaggi e i rifiuti da imballaggio.
2 HDPE	Indica che il prodotto è realizzato utilizzando polietilene ad alta densità.
PHT DEHP	Indica che il prodotto contiene ftalati, nello specifico ftalato di bis(2-etilesile) (DEHP).

Restituzione del prodotto usato

Se per qualsiasi motivo fosse necessario restituire questo prodotto a Terumo BCT, Inc., prima di procedere con la spedizione richiedere a Terumo BCT un'autorizzazione ritorno merce (RGA, Returned Goods Authorization).

Per ottenere istruzioni relative alla pulizia e ai materiali di imballaggio, compresi gli opportuni contenitori di spedizione, l'etichettatura e il numero RGA, rivolgersi al reparto Quality Assurance di Terumo BCT.

L'ADEGUATA PREPARAZIONE E IDENTIFICAZIONE DEL DISPOSITIVO PER LA RESTITUZIONE AL PRODUTTORE È RESPONSABILITÀ DELLA STRUTTURA SANITARIA.

Per informazioni sulla restituzione di prodotti e i reclami, contattare il distributore locale.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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사용 목적

Spectra Optia Apheresis 시스템의 사용 목적은 치료적 혈액성분 분반술 (Apheresis) 애플리케이션입니다. Spectra Optia 교환 세트는 Spectra Optia Apheresis 시스템과 함께 사용하도록 설계되었습니다.

Spectra Optia Apheresis 시스템 운영자 설명서를 참조하여 금기사항, 부작용, 경고사항, 주의사항 및 운영 지침에 관한 전체 내용을 확인하십시오.

경고

1. Terumo BCT에서 제조한 튜빙 세트에는 DEHP가 함유되어 있습니다. 일반적으로 구강 경로를 통해 DEHP에 노출된 설치류 동물에 관한 선별 연구에서는 태아 발달 중 남성 생식 기관에 잠재적으로 해로운 효과를 미칠 수 있다는 결과가 나왔습니다. 이러한 이유로 임산부 또는 수유부 및 아동을 포함한 환자군은 DEHP 노출의 잠재적으로 해로운 효과에 있어서 가장 위험한 집단으로 간주됩니다. 그러나 정맥 DEHP에 노출된 그 밖의 포유류 및 인간을 대상으로 한 연구 중 비슷한 결과를 나타낸 연구는 지금까지 없었습니다. 규제 기관에서는 DEHP 노출과 연관된 위험보다 필요한 Procedure를 수행하지 않는 위험이 더 크다는 점을 언급했습니다. 환자에게 미치는 이 위험을 해소하는 것이 치료를 맡은 의사의 책임입니다.

주의 사항

1. **재사용 불가:** 재사용 불가 기호가 붙은 Terumo BCT에서 제조한 튜빙 세트는 일회용으로 제조되었으며 재처리 또는 재사용할 수 없습니다. 세트를 재처리하거나 재사용하면 Terumo BCT에서는 세트의 기능 또는 무균 상태를 보장할 수 없습니다.
2. 튜빙 세트의 혈액과 용액 경로는 산화에틸렌으로 소독되며 비발열성입니다.다음 조건들 중 어느 하나라도 존재할 경우, 세트를 사용하지 마십시오.
   - 튜빙이 심하게 꼬여 있는 경우.
   - 튜빙 세트가 부정확하게 조립된 것처럼 보이는 경우.
   - 튜빙 세트가 손상된 경우.
   - 클램프가 라인에서 하나라도 닫혀 있는 경우.
3. 카세트를 내리거나 세트를 프라임 하지 않는 한, 운영자는 Procedure 진행 24시간 전에 튜빙 세트를 장착할 수 있습니다. 일단 카세트를 내리거나 세트를 프라임하면, 운영자는 반드시 동일한 작업 교대조 동안 그 세트를 사용해야 합니다.
4. 튜빙 세트의 손상을 피하도록 원심분리기에 장착하기 위해 채널을 접을 때 튜빙을 잡아 늘리지 마십시오.
5. 채널을 필러에 장착할 때 손가락만 사용하십시오. 채널에 구멍이 나는 일이 없도록, 날카로운 물체는 절대 사용하지 마십시오.
6. 4개 관이 있는 튜빙의 Inlet 라인을 Sealing하지 마십시오. 라인을 Sealing하면 세트를 제거하기 위해 카세트를 들어 올릴 때 튜빙 세트 작동에 문제가 생길 수 있습니다.
7. 모든 루어 연결부가 안전하지 확인하십시오.
8. 엔드 캡이 제 자리에 없는 경우, 교환 세트를 사용하지 마십시오.
9. 사용하지 않은 루어(Remove Bag에 있음)의 캡은 그대로 두어 용액 유출을 방지하십시오. 캡이 꼭 들어맞게 위치하는지 확인하십시오.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Spectra Optia Apheresis 시스템 운영자 설명서를 참조하십시오.

기호 및 인증

기호	정의
	이 기호에 있는 네모 안의 수량은 제품의 수량을 나타냅니다.
	이 기호의 특정 날짜는 제품의 만기일을 나타냅니다.
PYRO	이 기호는 제품이 비발열성임을 나타냅니다.
STERILE EO	이 기호는 산화에틸렌(EtO)를 사용하여 용액 경로를 소독했음을 나타냅니다.
	이 기호는 사용 전에 사용지침을 반드시 읽어야 함을 나타냅니다.
	이 기호의 특정 날짜는 제조 날짜(또는 제품을 소독한 경우 소독 날짜)를 나타냅니다.
REF	이 기호의 번호는 제품 카탈로그 번호를 나타냅니다.
	재사용 불가: 재사용 불가 기호가 붙은 Terumo BCT에서 제조한 튜빙 세트는 일회용으로 제조되었으며 재처리 또는 재사용할 수 없습니다. 세트를 재처리하거나 재사용하면 Terumo BCT에서는 세트의 기능 또는 무균 상태를 보장할 수 없습니다.
Rx Only	이 기호는 처방에 의해서만 제품을 사용할 수 있음을 나타냅니다.
CE 0086	본 장치는 의료 장치에 관한 1993년 6월 14일자 European Council Directive 93/42/EEC를 준수하여 제조되었습니다. 인증기관(Notified Body) 번호 0086이 적힌 본 마크는 유럽 공동체에서 해당 장치에 대한 영국 표준 협회의 승인을 획득했음을 나타냅니다.
LOT	이 기호의 번호는 제품 로트 번호를 나타냅니다.
	이 기호의 제조업체 명은 제품의 제조업체를 나타냅니다.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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기호	정의
	이 기호는 제품이 직사광선을 피해야 한다는 것을 나타냅니다.
	이 기호는 제품에 물기가 닿으면 안 됨을 나타냅니다.
	이 기호는 제품의 포장이 유럽 포장 및 포장 쓰레기 지침 94/62/EC에 따랐음을 나타냅니다.
HDPE	이 기호는 제품이 고밀도 폴리에틸렌으로 제조되었음을 나타냅니다.
PHT DEHP	이 기호는 제품에 프탈레이트, 특히 디에틸헥실(2-ethylhexyl)프탈레이트(DEHP)가 함유되었음을 나타냅니다.

사용한 제품의 반환

어떤 이유에서건 본 제품을 Terumo BCT, Inc.로 반환해야 할 경우, 배송하기 전에 Terumo BCT의 반품 인가(RGA 번호)를 받아야 합니다.

적절한 배송 컨테이너, 올바른 라벨 표시와 RGA 번호를 비롯한 제품의 Cleaning 및 Material에 관한 지침은 Terumo BCT Quality Assurance 부서로부터 받으실 수 있습니다.

반품 배송 대상 제품을 적절히 준비하고 확인하는 것은 보건의료 기관의 책임입니다.

반품과 제품 불만사항에 관한 정보를 원하시면 지역 담당자에게 연락해 주십시오.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Beoogd gebruik

Section 3 - 225

Het Spectra Optia® aferesesysteem is bedoeld voor gebruik in therapeutische aferesetoepassingen. De Spectra Optia® uitwisselingsset is bedoeld voor gebruik met het Spectra Optia® aferesesysteem.

Raadpleeg de gebruikershandleiding van het Spectra Optia® aferesesysteem voor een volledige lijst met contra-indicaties, bijwerkingen, waarschuwingen, aanmaningen tot voorzichtigheid en gebruiksaanwijzingen.

Waarschuwing

1. Bij Terumo BCT geproduceerde slangensets bevatten DEHP. Resultaten van bepaalde onderzoeken onder knaagdieren die aan DEHP werden blootgesteld (gewoonlijk via orale weg), hebben aangetoond dat er een risico bestaat van schadelijke effecten voor de mannelijke voortplantingsorganen tijdens de ontwikkeling van de foetus. Daarom worden patiëntgroepen met onder andere vrouwen die zwanger zijn of borstvoeding geven en kinderen beschouwd als de hoogste risicogroepen voor potentieel schadelijke effecten van blootstelling aan DEHP. Er zijn tot op heden echter geen andere onderzoeken met andere zoogdieren of mensen naar blootstelling aan DEHP uitgevoerd met vergelijkbare resultaten. Regelgevende instanties hebben opgemerkt dat het risico van het niet doen van een benodigde procedure veel groter is dan het risico dat gepaard gaat met blootstelling aan DEHP. De behandelend arts heeft de verantwoordelijkheid om dit risico voor de patiënten af te wegen.

Aanmaningen tot voorzichtigheid

1. **Niet voor hergebruik:** Slangensets die door Terumo BCT zijn vervaardigd en het symbool Niet voor hergebruik hebben, zijn uitsluitend bestemd voor eenmalig gebruik en mogen niet opnieuw worden verwerkt of opnieuw worden gebruikt. Terumo BCT kan de functionaliteit of steriliteit van de set niet garanderen als deze opnieuw is verwerkt of wordt gebruikt.
2. De bloed- en vloeistoftrajecten van de slangenset zijn met ethyleenoxide gesteriliseerd en zijn niet-pyrogeen. Gebruik de slangenset niet als zich een van de volgende condities voordoet:
   - De slangen vertonen ernstige knikken.
   - De slangenset lijkt niet op de juiste wijze te zijn samengesteld.
   - De slangenset is beschadigd.
   - Een of meer klemmen op de lijnen zijn gesloten.
3. U kunt de slangenset maximaal 24 uur vóór de procedure laden, als u de cassette maar niet omlaag brengt of de set voorvult. Zodra u de cassette omlaag brengt of de set voorvult, moet u de set tijdens dezelfde dienst gebruiken.
4. Rek de slang niet uit wanneer u het kanaal vouwt om het in de centrifuge te installeren. Hierdoor kan de slangenset beschadigd raken.
5. Gebruik alleen uw vingers als u het kanaal in de vuller laadt. Gebruik hiervoor nooit een scherp voorwerp; daarmee zou u het kanaal kunnen doorboren.
6. De afnamelijn van de slang met vier lumens mag u niet dichtlassen. Door het dichtlassen van de lijn kan er een fout optreden in de slangenset zodra u de cassette omhoog brengt om de set te verwijderen.

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7. Verzeker u ervan dat alle luer-aansluitingen goed vastzitten.
8. Gebruik de uitwisselingsset niet als de afdekkapjes ontbreken.
9. Laat het kapje op de niet-gebruikte luer (op de verwijderzak) zitten om vloeistoflekken te voorkomen. Zorg ervoor dat het kapje goed vastzit.

Procedures voor gebruik

Zie de gebruikershandleiding van het Spectra Optia® aferesesysteem.

Symbolen en certificeringen

Symbool	Definitie
	Geeft de producthoeveelheid aan, wanneer de hoeveelheid in het vak wordt weergegeven.
	Geeft de uiterste gebruiksdatum van het product aan, wanneer een specifieke datum wordt vermeld.
PYRO	Geeft aan dat het product niet-pyrogeen is.
STERILE EO	Geeft een met ethyleenoxide (EtO) gesteriliseerd steriel vloeistoftraject aan.
	Geeft aan dat de gebruiker vóór gebruik de gebruiksaanwijzing moet lezen.
	Geeft de fabricagedatum (of sterilisatiedatum, als het product steriel is) aan, wanneer een specifieke datum wordt vermeld.
REF	Geeft het catalogusnummer van het product aan, wanneer een nummer wordt vermeld.
	Niet voor hergebruik: Slangensets die door Terumo BCT zijn vervaardigd en het symbool Niet voor hergebruik hebben, zijn uitsluitend bestemd voor eenmalig gebruik en mogen niet opnieuw worden verwerkt of opnieuw worden gebruikt. Terumo BCT kan de functionaliteit of steriliteit van de set niet garanderen als deze opnieuw wordt verwerkt of gebruikt.
Rx Only	Geeft aan dat het product uitsluitend op voorschrift verkrijgbaar is.

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Symbool	Definitie
CE 0086	Het apparaat is vervaardigd in overeenstemming met de Europese richtlijn 93/42/EEG van 14 juni 1993 inzake medische hulpmiddelen. Deze markering met het nummer 0086 van de keuringsinstantie duidt de goedkeuring aan van het British Standards Institute voor deze apparaten binnen de Europese Unie.
LOT	Geeft het lotnummer van het product aan, wanneer een nummer wordt vermeld.
	Geeft de fabrikant van het product aan, wanneer de naam van de fabrikant wordt vermeld.
	Geeft aan dat het product niet in direct zonlicht mag worden geplaatst.
	Geeft aan dat het product droog moet worden gehouden.
DER GRÜNE PUNKT	Geeft aan dat de verpakking van het product voldoet aan de Europese richtlijn 94/62/EC voor verpakking en verpakkingsafval.
2 HDPE	Geeft aan dat het product is vervaardigd uit polyethyleen met een hoge dichtheid (HDP).
PHT DEHP	Geeft aan dat het product ftalaten bevat, in het bijzonder DEHP Di(2-ethylhexyl)-ftalaat.

Gebruikte producten retourneren

Indien dit product om welke reden dan ook moet worden teruggezonden naar Terumo BCT, Inc., is een RGA-nummer (Returned Goods Authorization, toestemming voor retournering van producten) van Terumo BCT vereist voordat het product verzonden kan worden.

Instructies voor reiniging en materialen, waaronder geschikte verpakkingen voor transport, juiste etikettering en een RGA-nummer, zijn verkrijgbaar bij de afdeling voor kwaliteitsborging van Terumo BCT.

HET IS DE VERANTWOORDELIJKHEID VAN DE GEZONDHEIDSINSTELLING OM HET PRODUCT GOED VOOR TE BEREIDEN EN TE IDENTIFICEREN VOOR DE RETOURZENDING.

Neem contact op met uw plaatselijke vertegenwoordiger voor informatie over teruggezonden goederen en klachten over producten.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Tiltenkt bruk

Spectra Optia®-aferesesystemet er beregnet til bruk ved terapeutiske afereseanvendelser. Spectra Optia®-utskiftingssettet er beregnet til bruk sammen med Spectra Optia®-aferesesystem.

Vi henviser til Spectra Optia®-aferesesystemets brukerhåndbok for en fullstendig liste over kontraindikasjoner, bivirkninger, advarsler, forsiktighetsregler og bruksanvisninger.

Advarsel

1. Slangesett som er produsert av Terumo BCT, inneholder DEHP. Resultater fra utvalgte studier av gnagere som ble eksponert for DEHP (vanligvis via munnen), har vist potensielle skadelige effekter på mannlige reproduksjonsorganer under fosterutviklingen. Pasientgrupper som blant annet gravide eller ammende kvinner og barn anses derfor for å være de med størst risiko for potensielle skadelige effekter av eksponering for DEHP. Ingen studier som er utført frem til i dag, av pattedyr og mennesker eksponert for intravenøst DEHP, har imidlertid vist lignende resultater. Tilsynsorganer har bemerket at risikoen forbundet med manglende utførelse av en nødvendig prosedyre, er mye høyere enn risikoen forbundet med eksponering for DEHP. Det er den behandlende legens ansvar å veie opp denne risikoen for pasientene.

Forsiktighetsregler

1. **Skal ikke brukes flere ganger:** Slangesett fra Terumo BCT som er merket med symbolet som angir at det ikke skal brukes flere ganger, er engangsslangesett som ikke må resteriliseres eller brukes flere ganger. Terumo BCT kan ikke garantere at settet er sterilt eller vil fungere som det skal hvis det resteriliseres eller brukes flere ganger.
2. Slangesettets blod- og væskebaner er sterilisert med etylenoksid og er pyrogenfrie. Settet må ikke brukes hvis et av de følgende forhold observeres:
   - Det er synlige knekker på slangesettet.
   - Slangesettet ser ut til å være uriktig sammensatt.
   - Slangesettet er skadet.
   - Noen av klemmene på slangene er lukket
3. Slangesettet kan installeres inntil 24 timer før prosedyren så lenge kassetten ikke senkes eller settet primes. Etter at kassetten er senket eller settet primet, må settet brukes i løpet av samme arbeidsskift.
4. For å unngå skade på slangesettet må du ikke strekke slangen når kanalen brettes og installeres i sentrifugen.
5. Bruk bare fingrene når kanalen skal settes inn i filleren. En skarp gjenstand må ikke brukes da dette kan punktere kanalen.
6. Ikke forsegle inlet-slangen i multilumenslangen. Hvis du forsegler slangen, kan det lekke fra slangesettet når du hever kassetten for å ta ut settet.
7. Kontroller at alle luerkoblingene er forsvarlig festet.
8. Utskiftingssettet må ikke brukes hvis endehettene ikke er på plass.
9. La hetten på den ubrukte luerkoblingen (på fjerningsposen) sitte på for å hindre væskelekkasje. Kontroller at hetten sitter tett på.

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Det henvises til Spectra Optia®-aferesesystemets brukerhåndbok.

Symboler og sertifiseringer

Symbol	Definisjon
	Angir produktantallet når antallet står i ruten.
	Angir produktets utløpsdato når dette ledsages av en bestemt dato.
PYRO	Angir at produktet er ikke-pyrogent.
STERILE EO	Angir en steril væskebane ved bruk av etylenoksid (EtO).
	Angir at brukeren må lese bruksanvisningen før bruk.
	Angir produksjonsdatoen (eller steriliseringsdatoen hvis produktet er sterilt) når dette ledsages av en bestemt dato.
REF	Angir produktets katalognummer når dette ledsages av et nummer.
	Skal ikke brukes flere ganger: Slangesett fra Terumo BCT som er merket med symbolet som angir at det ikke skal brukes flere ganger, er engangsslangesett som ikke må resteriliseres eller brukes flere ganger. Terumo BCT kan ikke garantere at settet er sterilt eller vil fungere som det skal hvis det resteriliseres eller brukes flere ganger.
Rx Only	Angir at produktet kun må brukes etter forskrivning.
CE 0086	Utstyret er produsert i overensstemmelse med det europeiske rådsdirektivet 93/42/EØF av 14. juni 1993 om medisinsk utstyr. Dette produktet er merket med kodenummeret til meldt organ 0086, som betyr godkjennelse fra British Standards Institute for dette utstyret i Det europeiske fellesskap.
LOT	Angir produktets lotnummer når dette ledsages av et nummer.
	Angir produsenten av produktet når dette ledsages av produsentens navn.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definisjon
	Angir at produktet må holdes borte fra sollys.
	Angir at produktet må holdes tørt.
	Angir at produktemballasjen er i samsvar med det europeiske direktivet 94/62/EF om emballasje og emballasjeavfall.
	Angir at produktet er laget av polyetylen med høy tetthet.
	Angir at produktet inneholder ftalater, spesielt Di(2-etylheksyl)ftalat (DEHP).

Returnering av brukt produkt

Hvis produktet av en eller annen grunn må returneres til Terumo BCT, Inc., må du få et RGA-nummer (et nummer som tillater retur av produktet) fra Terumo BCT før produktet sendes.

Instruksjoner om rengjøring og emballasje, inkludert egnede beholdere til forsendelse av produktet, riktig merking og et RGA-nummer fås ved henvendelse til kvalitetssikringsavdelingen i Terumo BCT.

DET ER INSTITUSJONENS ANSVAR Å KLARGJØRE OG IDENTIFISERE PRODUKTET PÅ EGNET MÅTE FOR RETURNERING.

Kontakt den lokale representanten hvis du vil ha informasjon om returnerte varer og klager på produktet.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Przeznaczenie

System do aferezy Spectra Optia® jest przeznaczony do zastosowań w aferezie terapeutycznej. Zestaw do wymiany Spectra Optia® jest przeznaczony do stosowania z systemem do aferezy Spectra Optia®.

Pełną listę przeciwwskazań, działań niepożądanych, ostrzeżeń, przestróg oraz instrukcji użytkowania można znaleźć w Instrukcji obsługi systemu do aferezy Spectra Optia®.

Ostrzeżenie

1. Zestawy drenów produkowane przez firmę Terumo BCT zawierają DEHP. Wyniki wybranych badań prowadzonych na gryzoniach poddanych działaniu DEHP (zazwyczaj poprzez drogę pokarmową) wykazały możliwość wystąpienia szkodliwego wpływu na męskie organy płciowe podczas rozwoju płodowego. Z tego powodu kobiety w ciąży lub karmiące piersią oraz dzieci są uważane za najbardziej narażone na potencjalny szkodliwy wpływ ekspozycji na DEHP. Żadne badania przeprowadzone do tej pory na innych ssakach lub u ludzi poddanych działaniu DEHP podanego dożylnie nie dały jednak podobnych wyników. Organy regulacyjne stwierdziły, że ryzyko niewykonania potrzebnego zabiegu znacznie przewyższa ryzyko związane z ekspozycją na DEHP. Lekarz prowadzący leczenie jest odpowiedzialny za rozważenie tego ryzyka u swoich pacjentów.

Przestrogi

1. **Nie używać ponownie:** Zestawy drenów wytwarzane przez firmę Terumo BCT, oznaczone symbolem „Nie używać ponownie”, przeznaczone są do jednorazowego użytku i nie należy ich przygotowywać do powtórnego użytku ani używać ponownie. Firma Terumo BCT nie może zapewnić funkcjonalności ani sterylności zestawu jeśli był on przygotowany do powtórnego użytku lub używany ponownie.
2. Ścieżki płynów i krwi zestawu drenów są wyjałowione za pomocą tlenku etylenu i są niepirogenne. Nie należy używać zestawu, jeżeli zachodzi którakolwiek z poniższych okoliczności:
   - Na drenach widoczne są wyraźne zagięcia.
   - Zestaw drenów wydaje się być niepoprawnie zmontowany.
   - Zestaw drenów jest uszkodzony.
   - Jakiekolwiek zaciski na liniach są zamknięte.
3. Zestaw drenów można załadować do 24 godzin przed rozpoczęciem procedury, pod warunkiem, że kaseta nie zostanie opuszczona i zestaw nie zostanie wypełniony. Po opuszczeniu kasety lub wypełnieniu zestawu należy wykorzystać zestaw podczas tej samej zmiany roboczej.
4. Nie wolno rozciągać drenu przy składaniu kanału w celu umieszczenia go w wirówce, gdyż grozi to uszkodzeniem zestawu drenów.
5. Kanał należy ładować do talerza wirówki, używając wyłącznie palców. Aby uniknąć przedziurawienia kanału, nie wolno korzystać z ostrych przedmiotów.
6. Nie należy zgrzewać linii napływu w drenie czteroświatłowym. Zgrzanie tej linii może spowodować awarię zestawu drenów w momencie podnoszenia kasety w celu wyładowania zestawu.

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7. Należy upewnić się, czy wszystkie złącza typu luer są ściśle dopasowane.
8. Nie należy używać zestawu do wymiany, jeżeli nasadki nie są na swoich miejscach.
9. Nie należy zdejmować nasadki z nieużywanego złącza typu luer (na worku eliminacyjnym), aby nie dopuścić do wycieku płynu. Należy upewnić się, czy nasadka jest dokładnie dopasowana.

Procedury w zakresie stosowania

Patrz Podręcznik operatora systemu do aferezy Spectra Optia®.

Symbole i certyfikaty

Symbol	Definicja
	Jeśli w kwadracie podano liczbę, symbol oznacza liczbę sztuk produktu.
	Oznacza datę przydatności produktu, jeśli obok podano określoną datę.
PYRO	Oznacza, że produkt jest niepirogenny.
STERILE EO	Oznacza jałową ścieżkę płynu po sterylizacji tlenkiem etylenu (EO).
	Oznacza, że przed zastosowaniem produktu konieczne jest przeczytanie instrukcji dotyczącej stosowania.
	Oznacza datę produkcji (lub datę sterylizacji, w przypadku gdy produkt jest jałowy), jeśli obok podano określoną datę.
REF	Oznacza numer katalogowy produktu, jeśli obok podano numer.
	Nie używać ponownie: Zestawy drenów wytwarzane przez firmę Terumo BCT, oznaczone symbolem „Nie używać ponownie”, przeznaczone są do jednorazowego użytku i nie należy ich przygotowywać do powtórnego użytku ani używać ponownie. Firma Terumo BCT nie może zapewnić funkcjonalności ani sterylności zestawu, jeśli był on przygotowany do powtórnego użytku lub używany ponownie.
Rx Only	Oznacza, że produkt można stosować tylko na receptę.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definicja
CE 0086	Urządzenie wyprodukowano zgodnie z dyrektywą Rady Europejskiej 93/42/EWG z 14 czerwca 1993 roku dotyczącą wyrobów medycznych. Znak ten zawiera numer jednostki notyfikowanej 0086, świadczący o zatwierdzeniu tych urządzeń do użytku we Wspólnocie Europejskiej przez British Standards Institute.
LOT	Oznacza numer serii produktu, jeśli obok podano numer.
	Oznacza producenta produktu, jeśli obok podano nazwę producenta.
	Oznacza, że produkt musi być chroniony przed światłem słonecznym.
	Oznacza, że produkt musi być chroniony przed wilgocią.
DER GRÜNE PUNKT	Oznacza, że opakowanie produktu jest zgodne z europejską dyrektywą nr 94/62/WE w sprawie opakowań i odpadów opakowaniowych.
2 HDPE	Oznacza, że produkt jest wykonany z polietylenu o dużej gęstości.
PHT DEHP	Oznacza, że produkt zawiera ftalany, w szczególności ftalan di(2-etyloheksylu) (DEHP).

Zwrot używanego produktu

Jeżeli z dowolnej przyczyny produkt trzeba zwrócić do firmy Terumo BCT, Inc., przed wysyłką wymagane jest otrzymanie z firmy Terumo BCT, Inc. autoryzacji zwracanych towarów (numer RGA).

Wskazówki dotyczące czyszczenia i materiałów, w tym odpowiednich pojemników transportowych, odpowiedniego oznakowania i numeru RGA, można uzyskać w Dziale Zapewniania Jakości (Quality Assurance Department) firmy Terumo BCT.

ODPOWIEDZIALNOŚĆ ZA WŁAŚCIWE PRZYGOTOWANIE I OZNAKOWANIE PRODUKTU DO WYSYŁKI ZWROTNEJ SPOCZYWA NA ZAKŁADZIE OPIEKI ZDROWOTNEJ.

Informacji na temat zwrotów i reklamacji produktów udziela lokalny przedstawiciel firmy.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Finalidade

O Sistema de Aférese Spectra Optia foi desenvolvido para uso em aplicações de aférese terapêutica. O conjunto para troca terapêutica Spectra Optia deve ser usado com o Sistema de Aférese Spectra Optia.

Consulte o Manual do Operador do Sistema de Aférese Spectra Optia para ver uma lista completa de contraindicações, efeitos adversos, advertências, avisos de cuidado e instruções de operação.

Advertência

1. Os conjuntos fabricados pela Terumo BCT contêm DEHP. Resultados de estudos selecionados de roedores expostos a DEHP (geralmente por via oral) têm mostrado efeitos potencialmente nocivos a órgãos reprodutores masculinos durante o desenvolvimento fetal. Em virtude disso, os grupos de pacientes que incluírem mulheres grávidas ou amamentando e crianças serão considerados como sendo de maior risco para efeitos nocivos potenciais de exposição a DEHP. No entanto, nenhum estudo realizado até o momento envolvendo outros mamíferos e seres humanos expostos a DEHP intravenoso mostrou resultados semelhantes. Os órgãos regulamentadores salientaram que o risco de não fazer um procedimento necessário é muito maior do que o risco associado à exposição a DEHP. Cabe ao médico responsável pelo tratamento avaliar esse risco para seus pacientes.

Cuidados

1. **Uso único:** os conjuntos fabricados pela Terumo BCT com o símbolo "uso único" destinam-se a apenas uma utilização e não devem ser reprocessados ou reutilizados. A Terumo BCT não pode garantir a funcionalidade ou esterilidade do conjunto se ele for reprocessado ou reutilizado.
2. As vias de sangue e de líquido do conjunto são esterilizadas com óxido de etileno e não são pirogênicas. Não use o conjunto se alguma das seguintes condições for verdadeira:
   - Se houver torções acentuadas aparentes nos tubos.
   - Se o conjunto parecer estar montado incorretamente.
   - Se o conjunto estiver danificado.
   - Se alguma pinça estiver fechada nas linhas.
3. É possível carregar o conjunto até 24 horas antes do procedimento se o cassete não for abaixado e não for feito o prime do conjunto. Assim que você abaixar o cassette ou preparar o conjunto, o conjunto deverá ser usado no mesmo turno de trabalho.
4. Não estique a tubulação ao dobrar o canal para instalá-lo na centrífuga, a fim de evitar danos ao conjunto.
5. Use apenas seus dedos para carregar o canal no prato de separação. Para evitar puncionamento do canal, nunca use um objeto pontiagudo.
6. Não vede a linha de entrada da tubulação de quatro lumens. Se a linha for vedada, o conjunto pode falhar ao ser levantado do cassete para descarregar o conjunto.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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7. Verifique se todas as conexões do bico luer estão firmes.

8. Não use o conjunto para troca terapêutica se as tampas das extremidades não estiverem no lugar.

9. Deixe a tampa no luer não utilizado (na bolsa de remoção) para evitar vazamento de líquido. Verifique se a tampa está firmemente encaixada.

Procedimentos de uso

Consulte o Manual do operador do Sistema de Aférese Spectra Optia.

Símbolos e certificações

Símbolo	Definição
	Indica a quantidade de produto quando a quantidade está inserida no quadrado.
	Indica a data de validade do produto quando acompanhado de uma data especifica.
PYRO	Indica que o produto é apirogênico.
STERILE EO	Indica um caminho de líquido esterilizado usando óxido de etileno (EtO).
	Indica que o usuário deve ler as instruções de utilização antes de usar o produto.
	Indica a data de fabricação (ou data de esterilização, se o produto for esterilizado) quando acompanhado de uma data específica.
REF	Indica o número de catálogo do produto quando acompanhado do número correspondente.
	Uso único: os conjuntos fabricados pela Terumo BCT com o símbolo "uso único" destinam-se a apenas uma utilização e não devem ser reprocessados ou reutilizados. A Terumo BCT não pode garantir a funcionalidade ou esterilidade do conjunto se ele for reprocessado ou reutilizado.
Rx Only	Indica que este produto deve ser utilizado exclusivamente mediante receita médica.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Símbolo	Definição
CE 0086	O dispositivo é fabricado em conformidade com a Diretriz 93/42/CEE do Conselho Europeu, de 14 de junho de 1993, relativa aos dispositivos médicos. Esta marca tem o Número de Corpo Notificado de 0086 indicando a aprovação pelo Instituto Britânico de Normas para esses dispositivos dentro da União Europeia.
LOT	Indica o número de lote do produto quando acompanhado do número correspondente.
	Indica o fabricante do produto quando acompanhado pelo nome do fabricante.
	Indica que o produto deve ficar protegido da luz solar.
	Indica que o produto deve ser mantido seco.
DER GRÜNE PUNKT	Indica que a embalagem do produto está em conformidade com a Diretriz Europeia 94/62/CE, relativa a embalagens e resíduos de embalagens.
2 HDPE	Indica que o produto é feito de polietileno de alta de densidade.
PHT DEHP	Indica que o produto contém ftalatos, especificamente Di(2-etilexil)ftalato (DEHP).

Devolução de produto usado

Se, por algum motivo, for necessário devolver este produto à Terumo BCT, Inc., será preciso obter uma Autorização para Devolução de Produtos (RGA) da Terumo BCT antes do embarque.

Instruções de limpeza e materiais, inclusive de contêineres apropriados para envio, etiquetagem adequada e um número de RGA podem ser obtidos junto ao Departamento de Garantia de qualidade da Terumo BCT.

É RESPONSABILIDADE DA INSTITUIÇÃO DE SAÚDE PREPARAR E IDENTIFICAR ADEQUADAMENTE O PRODUTO PARA O ENVIO COMO DEVOLUÇÃO.

Entre em contato com o representante local para obter informações sobre mercadorias devolvidas e reclamações sobre produtos.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Назначение

Сепаратор Spectra Optia предназначен для выполнения терапевтических процедур афереза. Комплект для обмена Spectra Optia предназначен для использования в сепараторе Spectra Optia..

Полный список противопоказаний, побочных эффектов, предупреждений, предостережений и инструкций по эксплуатации см. в Кратком руководстве по эксплуатации сепаратора Spectra Optia.

Предупреждение

1. Комплекты магистралей, произведенные компанией Terumo BCT, содержат ДЭГФ. Результаты отдельных исследований на грызунах, получавших ДЭГФ (обычно оральным путем), показали потенциально негативное воздействие на мужские репродуктивные органы во время развития плода. В связи с этим группы пациентов, в которые входят беременные или кормящие женщины или дети, считаются наиболее подверженными риску потенциально вредного действия ДЭГФ. При этом на сегодняшний день ни одно исследование с участием других млекопитающих и человека, подвергавшихся действию ДЭГФ после внутривенного введения, подобных результатов не дало. Регулирующими органами было отмечено, что риск невыполнения необходимой процедуры намного превышает риск, связанный с воздействием ДЭГФ. За устранение данного риска для пациентов отвечают лечащие врачи.

Предостережения

1. **Не предназначено для повторного использования:** комплекты магистралей, изготовленные компанией Terumo BCT и отмеченные символом «Не предназначено для повторного использования», предназначены исключительно для одноразового применения и не предназначены для повторной обработки или повторного использования. Компания Terumo BCT не может гарантировать функциональность или стерильность комплекта в случае его повторной обработки или повторного применения.

2. Просветы для крови и жидкости комплекта магистралей стерилизованы окисью этилена и апирогенны. Запрещается эксплуатация комплекта при любом из следующих условий:
   - Магистрали имеют значительные перегибы.
   - Комплект магистралей собран неправильно.
   - Комплект магистралей поврежден.
   - Любые зажимы на линиях закрыты.

3. Комплект магистралей можно установить за 24 часа до процедуры или позже при условии, что не будет опущена кассета или заполнен комплект. После опускания кассеты или заполнения комплекта его необходимо использовать в течение этой же рабочей смены.

4. Во избежание повреждения комплекта магистралей запрещается растягивать магистрали при складывании канала, устанавливаемого в центрифугу.

5. Загружайте канал в профиль только пальцами. Во избежание прокалывания канала запрещается использовать острые предметы.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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6. Запрещается запаивать линию забора четырехпросветных магистралей. В случае запаивания линии извлечение кассеты для выгрузки комплекта может привести к отказу комплекта магистралей.

7. Убедитесь, что все коннекторы Люэра зафиксированы.

8. Запрещается эксплуатация комплекта для обмена, если заглушки не установлены.

9. Во избежание утечки жидкости не снимайте заглушку с неиспользованного коннектора Люэра (на мешке для отработанных жидкостей). Убедитесь, что заглушка установлена плотно.

Процедуры

См. Руководство по эксплуатации сепаратора Spectra Optia.

Символы и сертификаты

Обозначение	Значение
	Обозначает количество препарата, если количество указано в прямоугольнике.
	Обозначает дату истечения срока годности препарата, если указана конкретная дата.
PYRO	Обозначает, что препарат апирогенен.
STERILE EO	Обозначает, что линия подачи жидкости стерилизована окисью этилена (EtO).
	Обозначает, что перед применением пользователь должен ознакомиться с инструкцией по применению.
	Обозначает дату производства (или дату стерилизации, если препарат стерилен), если указана конкретная дата.
REF	Обозначает каталожный номер препарата, если указан соответствующий номер.
	Не предназначено для повторного использования: комплекты магистралей, изготовленные компанией Terumo BCT и отмеченные символом «Не предназначено для повторного использования», предназначены исключительно для одноразового применения и не предназначены для повторной обработки или повторного использования. Компания Terumo BCT не может гарантировать функциональность или стерильность комплекта в случае его повторной обработки или повторного применения.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Обозначение	Значение
Rx Only	Обозначает, что препарат предназначен для применения только по рецепту врача.
CE 0086	Устройство произведено в соответствии с директивой Совета Европы 93/42/EEC от 14 июня 1993 года, касающейся устройств, используемых в медицине. Данная отметка с номером Уполномоченного органа 0086 обозначает, что использование таких устройств на территории Европейского Союза одобрено Институтом стандартов Великобритании.
LOT	Обозначает номер партии препарата, если указан соответствующий номер.
	Обозначает производителя препарата, при указании названия производителя.
	Обозначает, что продукт необходимо хранить вдали от солнечного света.
	Обозначает, что продукт должен храниться в сухом месте.
DER GRÜNE PUNKT	Обозначает, что упаковка препарата соответствует требованиям Европейской директивы 94/62/EC в отношении упаковки и использованных упаковочных материалов.
2 HDPE	Обозначает, что продукт изготовлен из полиэтилена высокой плотности.
PHT DEHP	Обозначает, что продукт содержит фталаты, а именно ди(2-этилгексил)фталат (ДЭГФ).

Возврат использованного изделия

Если по какой-либо причине это изделие подлежит возврату в компанию Terumo BCT, Inc., то до отправки требуется получить разрешение на возврат товаров (номер РВТ) от компании Terumo BCT.

Инструкции по подготовке и другие материалы, в том числе о соответствующих транспортных контейнерах, надлежащей маркировке и номере РВТ, можно получить в отделе контроля качества компании Terumo BCT.

НАДЛЕЖАЩАЯ ПОДГОТОВКА И МАРКИРОВКА ИЗДЕЛИЯ ДЛЯ ОБРАТНОЙ ОТПРАВКИ ЯВЛЯЕТСЯ ОБЯЗАННОСТЬЮ МЕДИЦИНСКОГО УЧРЕЖДЕНИЯ.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Для получения информации о возврате дредуктиин и передаче жалоб относительно оборудования обратитесь в местное представительство компании.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Avsedd användning

Spectra Optia® Aferessystem är avsett för användning i terapeutiska aferesapplikationer. Spectra Optia® Utbytesset är avsett för använding med Spectra Optia® Aferessystem.

Användarhandboken för Spectra Optia® Aferessystem innehåller en fullständig förteckning över kontraindikationer, varningar, försiktighetsåtgärder, biverkningar och bruksanvisningar.

Varning

1. Slangset som tillverkas av Terumo BCT innehåller DEHP. Resultat från utvalda studier på gnagare som exponerats för DEHP (vanligtvis oralt) har påvisat potentiellt skadliga effekter på de manliga fortplantningsorganen under fosterutvecklingen. Därför betraktas patientgrupper med gravida eller ammande kvinnor och barn som mest utsatta för de potentiellt skadliga effekterna vid exponering för DEHP. Man har däremot inte, till dags dato, kunnat se liknande resultat i studier på andra däggdjur eller människor som har exponerats för DEHP intravenöst. Tillsynsmyndigheter har noterat att risken med att att avstå från att utföra en nödvändig procedur är långt större än den risk som är förenad med exponering för DEHP. Det är den behandlingsansvarige läkarens ansvar att balansera riskerna för sina patienter.

Försiktighetsåtgärder

1. **Får ej återanvändas:** Slangset som tillverkats av Terumo BCT och som är märkta med symbolen Får ej återanvändas är endast avsedda för engångsbruk och inte avsedda för ombearbetning eller återanvändning. Terumo BCT kan inte garantera setets funktionalitet och sterilitet om det ombearbetas eller återanvänds.
2. Slangsetets blod- och vätskebanor har steriliserats med etylenoxid och är icke-pyrogena. Använd inte setet under följande förhållanden:
   - Det finns märkbara fel på en slang.
   - Slangsetet är inte rätt hopsatt.
   - Slangsetet är skadat.
   - Någon klämma är stängd längs slangarna.
3. Du kan ladda slangsetet upp till 24 timmar före proceduren, bara du inte sänker kassetten eller fyller setet. När du sänker ned kassetten eller fyller setet, måste det användas under samma arbetsskift.
4. Undvik att skada slangsetet genom att inte dra i slangen när du viker ihop kanalen för att installera den i centrifugen.
5. Använd endast fingrarna när du laddar kanalen i påfyllaren. Använd aldrig spetsiga föremål, eftersom det kan leda till att det går hål på kanalen.
6. Förslut inte inflödesslangen i slangknippet (4-lumen). Om du försluter slangen kan slangsetet läcka när du höjer kassetten för att ladda ur slangsetet.
7. Kontrollera att alla Luer-anslutningar är säkrade.
8. Använd inte utbytessetet om ändskydden inte sitter på plats.
9. Låt locket sitta kvar på den luer-anslutning som är oanvänd (den på utbytespåsen) för att förhindra vätskeläckage. Se till att locket sitter fast ordentligt.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Se Användarhandboken för Spectra Optia® Aferessystem.

Symboler och certifikat

Symbol	Definition
	Anger antalet produkter när antalet finns i rutan.
	Anger produktens utgångsdatum när det förekommer tillsammans med ett specifikt datum.
PYRO	Produkten är pyrogenfri.
STERILE EO	Anger en vätskebana som steriliserats med etylenoxid (EtO).
	Anger att användaren måste läsa bruksanvisningen före användning.
	Anger tillverkningsdatum (eller steriliseringsdatum, om produkten är steril) när det åtföljs av ett specifikt datum.
REF	Anger produktens katalognummer när det åtföljs av ett nummer.
	Får ej återanvändas: Slangset som tillverkats av Terumo BCT och som är märkta med symbolen Får ej återanvändas är endast avsedda för engångsbruk och inte avsedda för ombearbetning eller återanvändning. Terumo BCT kan inte garantera setets funktionalitet och sterilitet om det ombearbetas eller återanvänds.
Rx Only	Anger att produkten endast får användas enligt läkares ordination.
CE 0086	Enheten är tillverkad i överensstämmelse med EEG-direktiv 93/42/EEG av den 14 juni 1993 om medicintekniska produkter. Den här märkningen har anmält organnummer 0086, vilket anger godkännande av British Standards Institute för dessa produkter inom EU.
LOT	Anger produktens partinummer när det åtföljs av ett nummer.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Symbol	Definition
	Anger produktens tillverkare när det förekommer tillsammans med tillverkarens namn.
	Anger att produkten inte får utsättas för solljus.
	Anger att produkten måste förvaras torrt.
	Anger att produktförpackningen uppfyller EU:s direktiv 94/62/EC rörande förpackningar och förpackningsavfall.
	Anger att produkten är tillverkad av HDPE-plast.
	Anger att produkten innehåller ftalater, närmare bestämt di-(2-etylhexyl)-ftalat (DEHP).

Retur av använd produkt

Om denna produkt av någon orsak måste returneras till Terumo BCT, Inc. behövs ett returgodsnummer (RGA-nummer) från Terumo BCT innan den returneras.

Instruktioner för rengöring och material, inklusive lämplig leveransförpackning, korrekta etiketter och ett RGA-nummer, kan fås från Terumo BCT:s avdelning för kvalitetssäkring.

DET ÄR SJUKVÅRDSINRÄTTNINGENS ANSVAR ATT PÅ LÄMPLIGT SÄTT FÖRBEREDA OCH IDENTIFIERA PRODUKTEN SOM SKA RETURNERAS.

Kontakta en lokal representant för information angående returnering av gods och reklamationer.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Kullanım Amacı

Spectra Optia Aferez Sistemi'nin, terapötik aferez uygulamalarında kullanılması amaçlanmıştır. Spectra Optia Değişim Setinin, Spectra Optia Aferez Sistemi ile kullanılması amaçlanmıştır.

Kontrendikasyonların, advers etkilerin, uyarıların, ikazların ve çalışma yönergelerinin tam listesi için, lütfen Spectra Optia Aferez Sistemi Kullanım Kılavuzu'na bakın.

Uyarı

1. Terumo BCT tarafından üretilen setler DEHP içerir. DEHP'ye maruz kalan (genellikle oral yoldan) kemirgengillerle gerçekleştirilen çalışmalardan seçilen sonuçlar, fetüs gelişimi sırasında erkek üreme organlarının gelişimine zararlı bir etki olasılığı bulunduğunu ortaya koymuştur. Bu nedenden ötürü, hamile veya emziren kadınlar ile çocukları içeren hasta grupları DEHP'ye maruz kalma durumunda olası zararlı etkilerden en çok etkilenecek grup olarak düşünülmektedir. Ancak, günümüze kadar gerçekleştirilen ve diğer memelilerin ve insanların intravenöz DEHP'ye maruz bırakıldığı çalışmalardan hiçbiri benzer sonuçlar göstermemiştir. Düzenleyici makamlar gerekli bir prosedürü uygulamamanın getirdiği riskin DEHP'ye maruz kalmakla ilişkili riskin çok üzerinde olduğuna dikkat çekmişlerdir. Hastalara yönelik risklerin dengelenmesi tedaviyi gerçekleştiren hekimin sorumluluğudur.

İkazlar

1. **Tekrar Kullanılmaz:** Tekrar kullanılmaz sembolünü taşıyan Terumo BCT üretimi hortum setleri sadece tek kullanımlıktır ve tekrar işlenmemeli veya tekrar kullanılmamalıdır. Terumo BCT, tekrar işlenmesi veya tekrar kullanılması durumunda setin işlevselliğini veya sterilitesini garanti edemez.
2. Hortum setinin kan ve sıvı yolları etilen oksitle sterilize edilmiştir ve pirojenik değildir. Aşağıdaki durumlardan biri mevcutsa seti kullanmayın:
   - Hortumda ciddi bükülmelerin olduğu görülüyorsa.
   - Hortum seti yanlış monte edilmiş görünüyorsa.
   - Hortum seti hasarlıysa.
   - Hatlardaki kıskaçlardan herhangi biri kapalıysa.
3. Kaseti indirmediğiniz veya seti doldurmadığınız sürece, hortum setini prosedürden 24 saat öncesine kadar yükleyebilirsiniz. Kaseti indirdikten veya seti doldurduktan sonra, seti aynı vardiyada kullanmalısınız.
4. Hortum setine zarar vermemek için, kemeri santrifüje takmak üzere katlarken hortumu esnetmeyin.
5. Kemeri kasnağa yüklerken yalnızca parmaklarınızı kullanın. Kemerin delinmesini önlemek için, asla keskin kenarlı bir nesne kullanmayın.
6. Dört lümenli hortumun alış hattını mühürlemeyin. Hattın mühürlenmesi, seti çıkarmak için kaseti yükselttiğinizde hortum setinde sorun oluşmasına neden olabilir.
7. Tüm luer bağlantıların sağlam olduğundan emin olun.
8. Uç başlıkları yerinde değilse Değişim Setini kullanmayın.
9. Sıvı sızıntısını engellemek için kullanılmayan (uzaklaştırma torbasındaki) luerin başlığını üzerinde bırakın. Başlığın sıkıca oturduğundan emin olun.

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Spectra Optia Aferez Sistemi Kullanım Kılavuzuna bakın.

Semboller ve Sertifikalar

Sembol	Tanım
	Miktar karenin içine yerleştirildiğinde, ürün miktarını belirtir.
	Yanında belirli bir tarih verildiğinde, ürünün son kullanma tarihini belirtir.
PYRO	Ürünün apirojen olduğunu belirtir.
STERILE EO	Etilen oksit (EtO) kullanılan steril bir sıvı yolunu belirtir.
	Kullanıcının uygulamadan önce kullanım talimatlarını okuması gerektiğini belirtir.
	Yanında belirli bir tarih verildiğinde, üretim tarihini (veya ürün sterilse sterilizasyon tarihini) belirtir.
REF	Yanında bir sayı verildiğinde, ürün katalog numarasını belirtir.
	Tekrar Kullanılmaz: Tekrar kullanılmaz sembolünü taşıyan Terumo BCT üretimi hortum setleri sadece tek kullanımlıktır ve tekrar işlenmemeli veya tekrar kullanılmamalıdır. Terumo BCT, tekrar işlenmesi veya tekrar kullanılması durumunda setin işlevselliğini veya sterilitesini garanti edemez.
Rx Only	Ürünün yalnız reçeteyle kullanıldığını belirtir.
CE 0086	Cihaz, tıbbi cihazlarla ilgili 14 Haziran 1993 tarihli ve 93/42/EEC sayılı Avrupa Konseyi Yönergesine uygun şekilde imal edilmektedir. 0086 Onaylanmış Kuruluş Numaralı bu işaret, bu cihazların Avrupa Topluluğu dahilinde İngiliz Standartları Enstitüsü tarafından onaylandığını göstermektedir.
LOT	Yanında bir sayı verildiğinde, ürün lot numarasını belirtir.
	Yanında üreticinin adı verildiğinde, ürünün üreticisini belirtir.

estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Sembol	Tanım
	Ürünün güneş ışığından uzak tutulması gerektiğini belirtir.
	Ürünün kuru halde tutulması gerektiğini belirtir.
	Ürün ambalajının, ambalaj ve ambalaj atıklarına ilişkin 94/62/EC sayılı Avrupa Direktifi ile uyumlu olduğunu belirtir.
	Ürünün Yüksek Yoğunluklu Polietilenden yapılmış olduğunu belirtir.
	Ürünün ftalatları, özellikle de Di(2-etilheksil) ftalatını (DEHP) içerdiğini belirtir.

Kullanılmış Ürünün İadesi

Bu ürünün herhangi bir nedenden ötürü Terumo BCT, Inc.'ye iade edilmesi gerekiyorsa, nakliyeden önce Terumo BCT'den malzeme iadesi izni (RGA numarası) alınması gerekir.

Uygun nakliye kutuları, etiketleme ve RGA numarası da dahil olmak üzere malzemeler ve temizleme ile ilgili talimatlar Terumo BCT Kalite Güvence Bölümünden alınabilir.

ÜRÜN İADE EDİLİRKEN ÜRÜNÜN NAKLİYE İÇİN UYGUN ŞEKİLDE HAZIRLANMASI VE TANIMLANMASI SAĞLIK KURUMUNUZUN SORUMLULUĞUDUR.

Malzemelerin iadesi ve ürünlerle ilgili şikayetler hakkında bilgi edinmek için lütfen yerel temsilcinizle temasa geçin.

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estions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8

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Attachment 13.4

Kit Label
Spectra Optia Exchange Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

Spectra Optia® Exchange Set
Jeu d'échange du Spectra Optia®
Set per scambio terapeutico del Spectra Optia®
Schlauchset für therapeutisches Austauschverfahren für das Spectra Optia®
Equipo de recambio terapeútico de Spectra Optia®
Uitwisselingsset voor het Spectra Optia®
Utbytesset för Spectra Optia®
Spectra Optia® Engangsslangesæt
Conjunto para troca do Spectra Optia
Utskiftingssett for Spectra Optia®
Spectra Optia® vaihtosarja
Výměnná souprava Spectra Optia®
Spectra Optia® Zestaw do Wymiany
Система для плазмафереза к сепаратору Spectra Optia
Σετ ανταλλαγής Spectra Optia®
Spectra Optia® Değiştirme Seti

再使用禁止

1

수혈용채혈세트(Spectra Optia Exchange Set (10220))
管理医療機器
遠心型血液成分分離装置用血液回路
スペクトラ オプティア用血液回路
Exchange セット1 セット

Sterile and non-pyrogenic fluid pathway. Do not use the set if the end caps are not in place. Read instructions for use before application. Sterilized with ethylene oxide. Intended for single use only. Do not resterilize. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

제품명:수혈용채혈세트. 수입원:㈜케이에스메디칼. 서울 강남구 도곡동 412-4 재경빌딩 2층 (T:02-2088-8814). 수입업허가번호:제1600호. 품목허가번호:제 수허 09-804호. 제조원:Terumo BCT, Inc.(미국). 사용목적,사용방법 및 사용상의 주의사항:사용설명서참조. 실온보관. 포장단위:낱개포장.사용기간:멸균일로부터 2년. 1회용 멸균방법: EO가스멸균. 본 제품은 "일회용 멸균의료기기"임. DEHP를 첨가한 PVC가 사용됨

この回路はエチレンオキサイド滅菌 / 非発熱性です。キャップが外れている場合は回路を使用しないで下さい。使用前には必ず添付文書をご参照ください。

製造販売業者：テルモＢＣＴ株式会社
東京都渋谷区恵比寿南1丁目7番8号 恵比寿サウスワン
製造業者：Terumo BCT, Inc.（米国）

医療機器認証番号 22200BZX00554000

EXPIRY DATE : 2015-04-01
사용기한
有効期限

MANUFACTURE DATE : 2013-04-01
제조년월일

CATALOG NO. REF : 10220
형명(모델명)
カタログ番号

LOT NO.: 04V1234
제조번호
ロット番号

PYRO STERILE EO

Rx Only CE 0086

Japan Product Code: 5020583102200

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Lakewood, CO 80215
MADE IN USA

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(01)05020583102200
(17)150401(10)04V1234

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 13.5

Case Label
Spectra Optia Exchange Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Spectra Optia® Exchange Sets
Jeu d'échange du Spectra Optia®
Set per scambio terapeutico del Spectra Optia®
Schlauchsets für ein therapeutisches Austauschverfahren für das Spectra Optia®
Equipos de recambio terapeútico de Spectra Optia®
Uitwisselingssets voor het Spectra Optia®
Utbytesset för Spectra Optia®
Spectra Optia® Engangsslangesæt
Conjuntos para troca do Spectra Optia
Utskiftingssett for Spectra Optia®
Spectra Optia® vaihtosarjat
Výměnná soupravy Spectra Optia®
Spectra Optia® Zestawy do Wymiany
Система для плазмафереза к сепаратору Spectra Optia
Σετ ανταλλαγής Spectra Optia®
Spectra Optia® Değiştirme Setleri
수혈용채혈세트(Spectra Optia Exchange Set (10220))
管理医療機器
遠心型血液成分分離装置用血液回路
スペクトラ オプティア用血液回路
Exchange セット6 セット

再使用禁止

6

Sterile and non-pyrogenic fluid pathway. Do not use the set if the end caps are not in place. Read instructions for use before application. Sterilized with ethylene oxide. Intended for single use only. Do not resterilize. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

제품명:수혈용채혈세트. 수입원:㈜케이에스메디칼. 서울 강남구 도곡동 412-4 재경빌딩 2층 (T:02-2088-8814). 수입업허가번호:제1600호. 품목허가번호:제 수허 09-804호. 제조원:Terumo BCT, Inc.(미국). 사용목적,사용방법 및 사용상의 주의사항:사용설명서참조. 실온보관. 포장단위:낱개포장.사용기간:멸균일로부터 2년. 1회용
멸균방법: EO가스멸균. 본 제품은 "일회용 멸균의료기기"임. DEHP를 첨가한 PVC가 사용됨

この回路はエチレンオキサイド滅菌 / 非発熱性です。キャップが外れている場合は回路を使用しないで下さい。使用前には必ず添付文書をご参照ください。
製造販売業者：テルモＢＣＴ株式会社
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製造業者：Terumo BCT, Inc.（米国）
医療機器認証番号 22200BZX00554000

EXPIRY DATE : 2015-04-01
사용기한
有効期限
MANUFACTURE DATE : 2013-04-01
제조년월일
CATALOG NO. REF :10220
형명(모델명)
カタログ番号
LOT NO.: 04V1234
제조번호
ロット番号

PYRO STERILE EO

Rx Only CE 0086

Japan Product Code: 5020583102200

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Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

Attachment 13.6

Draft RBCx Brochure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RED BLOOD CELL EXCHANGE

ADVANCING THERAPEUTIC APHERESIS AND CELL COLLECTIONS TO THE NEXT LEVEL OF PATIENT CARE

TERUMOBCT
Unlocking the Potential of Blood

DRAFT

SPECTRA OPTIA® APHERESIS SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Giving you procedural flexibility

The Spectra Optia system gives you the flexibility to perform multiple types of red blood cell exchange (RBCX) procedures. In addition to performing exchanges and depletions, it is the only system on the market that enables you to perform a combined depletion/exchange procedure.

Each RBCX procedure can be tailored to your specific patients' needs. The Spectra Optia system can be used to perform RBCX procedures for the transfusion management of sickle cell disease in adults and children.

PROCEDURE AND SYSTEM HIGHLIGHTS

Intuitive graphical user interface	Guides you through the RBCX procedure and automates the calculations Streamlines your procedure management with touch-screen instructions, simple data entry and procedure monitoring
Custom prime option	Clearly defined sequence that differentiates priming from the run targets
Flexible system	Gives you a choice of three procedures: exchanges, depletions and depletion/exchanges Helps you customize each procedure to meet individual patient needs Versatile software is designed for a wide range of device interaction preferences and operator skill levels
Procedural automation	Enables you to spend more time with patients
Large, durable wheels on pivoting casters	Makes maneuvering the system easy
Convenient data management	Stores procedure data to export or print Helps you minimize manual data transcription and address regulatory requirements

SYSTEM PERFORMANCE IN PATIENTS WITH SICKLE CELL DISEASE

The data below demonstrates how the Spectra Optia system accurately predicted the fraction of cells remaining (FCR) and the final patient hematocrit (Hct).

Parameters and Statistics	Patient Population (N = 60)
Actual to Calculated FCR	
Mean ± standard deviation	0.9 ± 0.2
Median (minimum, maximum)	0.9 (0.0, 1.3)
95% CI	0.9, 0.9
Pre-Treatment Hemoglobin S (HbS)	
Mean ± standard deviation	38.0 ± 12.8
Median (minimum, maximum)	36.5 (1.9, 71.8)
95% CI	34.7, 41.3
Post-Treatment Hemoglobin S (HbS)	
Mean ± standard deviation	13.9 ± 6.0
Median (minimum, maximum)	13.7 (0.0, 29.1)
95% CI	12.3, 15.4
Difference Between Targeted and Actual Final Hct	
Mean ± standard deviation	1.0 ± 0.1
Median (minimum, maximum)	1.0 (0.9, 1.3)
95% CI	1.0, 1.0

Notes:

Actual FCR = post procedure %HbS / pre-procedure %HbS

Calculated FCR = system-reported FCR at completion of the procedure, taking into account the actual amount of replacement RBCs given.

CI = confidence interval

The above table summarizes the results from the RBCX Procedure – Evaluation Study of the Spectra Optia® Apheresis System RBCX Protocol in Patients with Sickle Cell Disease.

Both pediatric and adult patients were evaluated in the multi-center, single-arm study and there were no statistically significant differences between the results of the patient populations. Additionally, there were no statistically significant differences between exchange and depletion/exchange procedures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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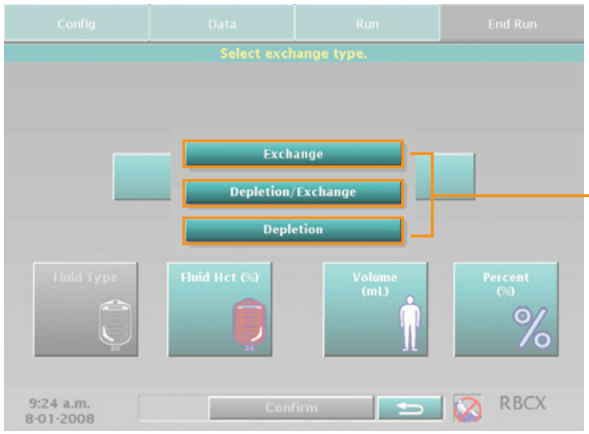
With the Spectra Optia system, you get helpful guidance through each step. The examples below illustrate the ease of setting up and running an RBCX procedure.



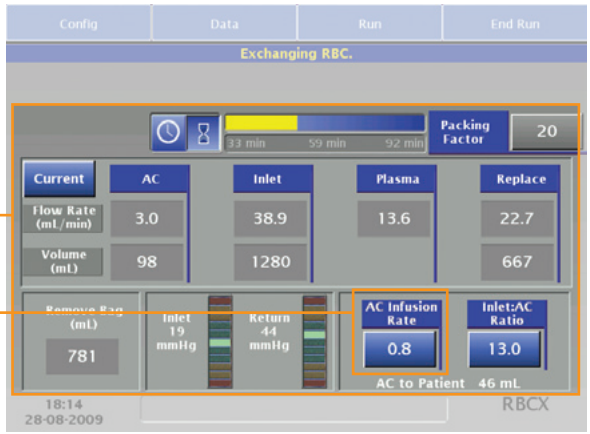
PROCEDURE TYPE SCREEN

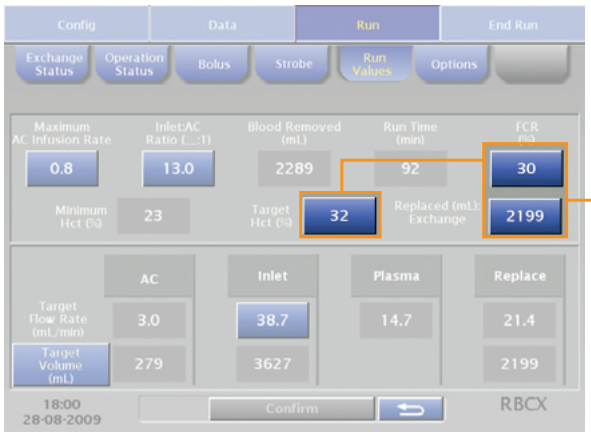
From this screen you can select the RBCX procedure type—exchange, depletion/exchange or depletion.

MAIN RUN SCREEN

Throughout your procedure, you can easily monitor progress and make modifications.

Anticoagulation (AC) infusion rate can easily be monitored and modified throughout the procedure.





RUN VALUES SCREEN

From this screen you enter the target fraction of cells remaining percentage (FCR%) or replacement fluid volume and the system will complete the other value.

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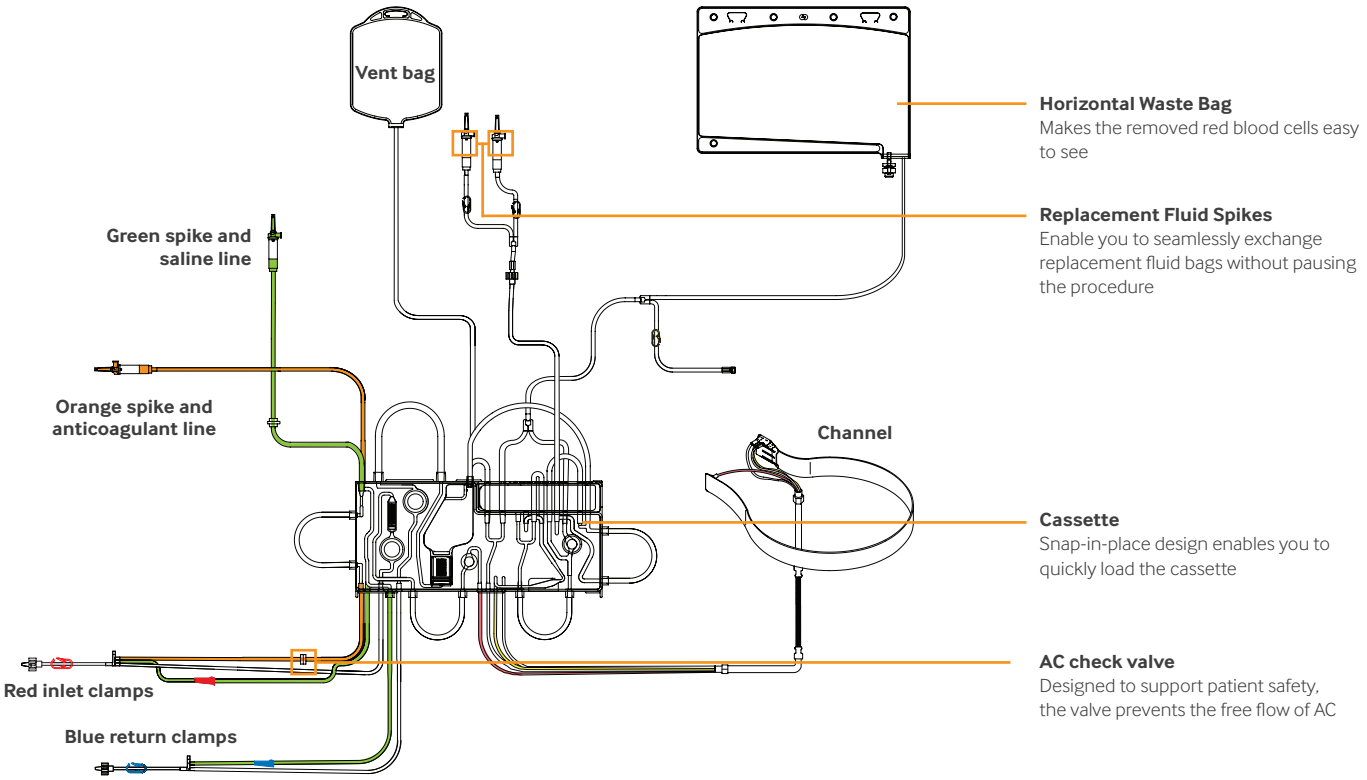

Low volume tubing set (Maximum ECV* = 185 mL)	Accommodates smaller patients and supports patient comfort and safety
Single set, multiple protocols	Performs RBCX procedures on the same tubing set used for therapeutic plasma exchange
Compact packaging	Minimizes the space required for storage
Color-coded components	Simplifies setup and operation

*Maximum ECV with reservoir filled to high-level sensor (maximum occurs under certain infrequent alarm conditions)

Working with you

Each and every interaction we have with you is important. By fostering open and ongoing relationships, we bring more value to you and the patients we're all focused on serving.

Even after the technology is in place, we continue to serve you by advancing apheresis through:

- Education and training
- Technical support
- Clinical support
- Customer support
- Users groups and professional networks

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14 Sterilization and Shelf Life

14.1 Sterilization Validation

Sterilization is conducted at Terumo BCT Sterilization Services in Lakewood, CO. This sterilization facility has been successfully validated to meet the requirements of ANSI/ AAMI/ISO 11135: 1-2007 - *Sterilization of health care products - Ethylene oxide – Part J: Requirements for development, validation and routine control of sterilization process for medical devices.* (b)(4) [redacted]

(b)(4) [redacted]

14.2 EtO Residual Toxicity

The Spectra Optia Exchange Set (#10220) has been adopted by equivalency for ethylene oxide (EtO) and out-gassing. The EtO sterilization process results in a sterility assurance level (SAL) of ≤ 10-6 in accordance with ANSI/ AAMI/ISO 11135-1:2007. The process used to outgas both disposables results in residuals ≤ 6 mg EtO and ≤ 6 mg ethylene chlorohydrin (ECH) which meet the requirements listed in ANSI/AAMI/ISO 10993-7:2008. The EtO sterilization and out-gassing evaluation for the Exchange Set is provided in **Attachment 14.2**.

14.3 Packaging and Shelf Life

(b)(4) [redacted]

Packaging verification was conducted to demonstrate that the packaging configuration for the Exchange Set passed transportation simulation testing in accordance with ISTA:2A guidelines. The Exchange Set is currently labeled with an expiry of two (2) years based on accelerated aging data, microbial barrier validation data, as well as time-zero (0) and accelerated shelf life data.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Testing

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Attachment 1

Visual Inspection observation Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

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Attachment 2

Barcode Observation Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

b) (4)

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Attachment 3

SUT/Pump Header/Loop/Channel testing Observation Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

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Attachment 4

AC testing Observation Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

b)(4) Testing

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Attachment 5

Flowrate Testing Raw Data

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15 Biocompatibility

The Spectra Optia Exchange Set is comprised of blood contact material that has been tested for biological reactivity according to the requirements of ISO 10993-1. These are the same raw materials and/or components as used in other the Terumo BCT manufactured disposable tubing sets that are 510(k) cleared. A report of the testing conducted for the Exchange Set is provided as **Attachment 15.1**.

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16 Software

Provided on the following pages is a software description for the Spectra Optia system following the order presented in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

Please that some documents included in this submission pre-date Terumo BCT and may contain headers with previous company names of CaridianBCT or Gambro BCT. Additionally, the Spectra Optia Apheresis System may be referenced within some documentation under its research and development name Therapeutic Apheresis Operating System or "TAOS."

16.1 Level of Concern

The Spectra Optia system is intended for use in therapeutic plasma exchange. Based upon the "G*uidance for the Content of Premarket Submissions for Software Contained in Medical Devices"*, issued on May 11, 2005, the level of concern of the Spectra Optia system is "Major".

16.2 Software Description

(b) (4)

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Changes to the currently licensed Spectra Optia system software were made to implement red blood cell exchange procedures. Detailed requirements are discussed below.

16.3 Device Hazard Analysis

The risks associated with this software design change were assessed using a Failure Mode, Effects and Criticality Analysis (FMECA) approach. The FMECA process for Terumo BCT is outlined in the steps below.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 16.8

Spectra Optia Safety Executive Design

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TERUMOBCT

Spectra Optia

Safety Executive Design

Revision 4.0

May 6, 2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

Spectra Optia® Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission

Attachment 16.10

(b) (4) [redacted] Software Development and Quality Assurance Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

Spectra Optia
Software Development and Quality Assurance Plan

Revision 2.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 16.11

Spectra Optia Verification Report for
Spectra Optia Red Blood Cell Exchange (RBCX)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

Spectra Optia® Apheresis System

Verification Report for Spectra Optia Red Blood Cell Exchange (RBCX)

Version 9.0 Software, Build 15.112

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17 Electrical Safety

Due to the fact that no changes to the Spectra Optia equipment have been made to accommodate the Spectra Optia RBCx protocol, electrical safety testing was not warranted.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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18 Performance Testing – Bench

A simulated use laboratory study was conducted to evaluate RBCX procedures performed on the Spectra Optia device as compared to the COBE Spectra system. This comparison was conducted using a panel of six "simulated patients" (represented by carefully constructed and controlled blood bags) and evaluated each device, with respect to its ability to achieve targeted clinical endpoints and included exchange, depletion and depletion/exchange procedures.

The primary outcome endpoint of the laboratory study was to measure the ability of each device to achieve targeted mid-run (depletion/exchange procedures) and end-of-run (all procedures) hematocrits. Hematocrit measurements were used as a surrogate endpoint for the fraction of (defective) cells remaining (FCR). Final results demonstrated that the Spectra Optia system achieved target hematocrits more accurately than did COBE Spectra. The full laboratory validation report is provided in **Attachment 18.1**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 18.1
Spectra Optia Apheresis System
Report Synopsis
RBCX Simulated-use Laboratory Testing

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CaridianBCT

Spectra Optia®Apheresis System

Report Synopsis
RBCX Simulated-use Laboratory Testing

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EXECUTIVE SUMMARY

Introduction and Background

CaridianBCT has developed a new therapeutic protocol for the Spectra Optia Apheresis System – Red Blood Cell Exchange (RBCX). The Spectra Optia device has been designed to perform with all of the therapeutic apheresis utility of the current COBE® Spectra Apheresis System. Both the Spectra Optia and COBE Spectra systems use centrifugal force to separate blood into plasma and cellular components.

The purpose of this validation report synopsis is to review the findings of the laboratory study designed to evaluate RBCX procedures conducted on the Spectra Optia device compared to the COBE Spectra system. This comparison was conducted using a panel of six "simulated patients" (represented by carefully constructed and controlled blood bags) and evaluated each device, with respect to its ability to achieve targeted clinical endpoints.

Study Objective

A laboratory-based, comparative study of the COBE Spectra and Spectra Optia systems was performed to compare Red Blood Cell Exchange procedures conducted on the two device platforms. RBCX procedures conducted using the Spectra Optia device include exchange, depletion and depletion/exchange.

Study Design: Simulated Patient Conditions

Blood bags representing a panel of six simulated patient conditions were prepared using controlled procedures for laboratory evaluation. The simulated conditions (blood bags) were carefully constructed to represent actual clinical patients that commonly present for each of the three RBCX procedure types (exchange, depletion, and depletion/exchange). Importantly, the simulated conditions represented patients with both large and small total blood volumes. Red Blood Cell Exchange procedures were then conducted for these six simulated conditions using both the COBE Spectra and Spectra Optia systems, respectively. Testing using this simulated patient panel was replicated three times on both platforms. In total, the laboratory validation included 36 RBCX procedures (6 simulated patients * 3 replications * 2 device platforms) each of which required an appropriately constructed blood bag (i.e., patient). Key RBCX procedure outcomes were compared across the apheresis systems using conventional parametric and nonparametric statistical techniques. The laboratory experiment was statistically sized, based on a noninferiority hypothesis, and was conducted in compliance with Good Clinical Practice Guidelines. To further represent an actual clinical practice setting, RBCX procedures conducted on the Spectra Optia system were performed by volunteer nurse apheresis operators from three U.S. academic medical centers. Lastly, additional Spectra Optia RBCX procedures were conducted using 42-day-old stored blood, waste sickle-cell blood and needle (vs. luer lock) connections to the blood bags, to further demonstrate the platform's robustness.

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Outcome Measures

The primary outcome measure was the ability of each device to achieve targeted mid-run (depletion/exchange procedures) and end-of-run (all procedures) hematocrits. Hematocrit measurements were used as a surrogate endpoint for the fraction of (defective) cells remaining (FCR).

Secondary outcome measures included fluid balance, hemolysis (measured for procedures conducted with waste sickle-cell blood, 42-day-old stored blood, and when using needles at high flow rates), and procedure time.

Results

With respect to the study's primary outcome measure, the Spectra Optia system achieved target hematocrits more accurately than did COBE Spectra. The median difference between the targeted and measured hematocrits was .56 hematocrit units for the Spectra Optia system vs. 1 hematocrit unit for the COBE Spectra device. While statistically significant in this carefully controlled laboratory study, this difference may not be appreciable or replicable in the clinical setting - where inaccuracies of other measurements, such as TBV and patient and replacement fluid hematocrits, may tend to obscure the improvement. Clearly, however, RBCX conducted on the Spectra Optia system performs similarly to COBE Spectra, with respect to this key measure.

For the study's secondary outcome measures (fluid balance, hemolysis, and procedure time), the two platforms performed essentially the same. Fluid balance measurements were equivalent for the two devices. The median difference between the targeted and observed fluid balance was 1.2% for the Spectra Optia system vs. 1.4% for COBE Spectra. No significant hemolysis was detected for Spectra Optia, even when day-old sickle-cell waste products or 42-day-old stored red blood cells (RBCs) were processed. Additionally, no significant hemolysis was detected when needles were used to access the simulated patient (blood bag) at high flow rates. Finally, procedure or "run" times were similar between the two devices.

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Description of Spectra Optia RBCX Procedures

The Spectra Optia RBCX protocol includes three procedure types:

1. *Exchange*, in which defective red blood cells (RBCs) are removed and replaced with healthy RBCs.

2. *Depletion*, in which excessive - generally not defective - RBCs are removed. A depletion can be thought of as an exchange, in which the hematocrit of the replacement solution is zero. For the more usual exchange, the replacement solutions are packed RBCs with hematocrits of between 55 and 80%.

3. *Depletion/Exchange*, in which defective RBCs are first depleted to a safe level and then the remaining defective RBCs are exchanged with healthy RBCs. This allows for a more efficient use of replacement RBCs, such that fewer units may be required or a greater depletion of defective cells may be effected with the available replacement units.

Benefits of Simulated-use Laboratory Validation Testing for RBCX procedures

The Spectra Optia's RBCX protocol is uniquely suited to laboratory validation. As described below, this suitability centers on (1) the similarity of the RBCX and Therapeutic Plasma Exchange (TPE) protocols as implemented on the Spectra Optia platform and, (2) the similarity of the RBCX protocol itself across the Spectra Optia and COBE Spectra systems.

Essential Similarities: TPE and RBCX on Spectra Optia.
The Spectra Optia system's RBCX protocol is analogous to its Therapeutic Plasma Exchange (TPE) procedure. The TPE procedure is used worldwide and received 510(k) clearance in 2007. Spectra Optia's RBCX procedure uses the same hardware (apheresis machine) and a disposable tubing set (the Spectra Optia Exchange Set), as does the TPE protocol. TPE and RBCX, conducted on the Spectra Optia platform, differ only with respect to system's embedded software.

Essential Similarities: RBCX on Spectra Optia and COBE Spectra.
As distinct from TPE, the efficiency of the exchange for RBCX does not vary and is, in fact, 100%, as virtually all of the red blood cells (RBCs) presented to the Spectra Optia or COBE Spectra systems are removed. As such, the underlying equations that control the exchange are the same for the two systems.

Given these key similarities within and across the two platforms, it is not necessary to run actual patient procedures to establish that the Spectra Optia RBCX protocol performs as

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designed and is functionally equivalent to the COBE Spectra. In fact, the addition of laboratory testing using "simulated patients" to routine clinical testing has a number of distinct advantages when the overriding objective is to compare the performance of the two apheresis devices.

Advantages of Laboratory Testing Using Simulated Patients.
Advantages of laboratory validation (LV) include the following:

- LV allows for the conduct of nearly identical, simulated-patient procedures on both the Spectra Optia and COBE Spectra devices.
- LV uniquely allows identical simulated-patient procedures to be conducted by multiple apheresis operators, including operators from multiple clinical sites.
- LV using simulated patients (blood bags) facilitates the more accurate determination of total blood volume (TBV). TBVs calculated by Spectra Optia or COBE Spectra systems are estimates; whereas, for a "simulated patient" (i.e., bag of blood), the TBV can be measured exactly.
- LV using simulated patients also facilitates the more accurate determination of patient hematocrit, replacement-fluid hematocrit, and the hematocrit of the removed red blood cells. As described in the experimental procedures, all of the study's hematocrit measurements were made in triplicate using the same automated counter. Although it is possible to measure hematocrits in triplicate in a clinical setting, this is, in reality, very difficult if not impossible to do – particularly, for multiple units of replacement RBCs.
- LV is free from the variation introduced by physiologic fluid shifts and/or red cell mobilization that can characterize actual clinical procedures.

Experimental Design

A panel of six simulated-patient conditions was designed to represent the presenting characteristics of typical large blood volume (adult) and small blood volume (pediatric) patients. This panel of simulated "patients" is shown in Table 1.

For these experiments, each simulated condition was represented by a bag of blood. The blood bag was constructed using pooled, type-matched, human-donor blood, with a specified volume and hematocrit. Red Blood Cell Exchange procedures were then conducted using these carefully constituted blood bags in place of actual patients.

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Table 1. Panel of Simulated Patient Conditions

Simulated Patient #	Type	Sex*	Ht (ft in)	Wt (lb)	Patient TBV	Starting Patient Hct	Replace Hct	Target Mid Hct	Target End Hct	Exchange Replace Volume
1	exchange	F	3'6	60	~1500	~27	~60	NA	30	~1000
2	exchange	F	5'2	162	~4000	~20	~65	NA	30	~1500
3	depletion/exchange	F	3'6	60	~1500	~30	~60	24	30	~750
4	depletion/exchange	F	5'5	210	~5000	~25	~80	20	35	~2000
5	depletion	F	3'6	60	~1500	~70	0	NA	50	NA
6	depletion	F	4'8	140	~3300	~70	0	NA	50	NA

NA, not applicable for this type of procedure

* Sex Ht and Wt were used only to define the desired patient TBV, males with slightly different ht and wt could have equally been chosen

Spectra Optia and COBE Spectra Comparison.

The panel of six simulated-patient conditions was run in triplicate on the COBE Spectra system by experienced CaridianBCT operators, and on the Spectra Optia platform by experienced apheresis nurses from three U.S. academic medical centers that routinely perform RBCX on the COBE Spectra. The key metrics were the accuracy with which each device met the targeted hematocrit and the accuracy with which each device maintained fluid balance at 100% at the end of the procedure. The necessary data were captured on case report forms for the Spectra Optia and COBE Spectra systems. Spectra Optia procedure times, alarms and device malfunctions were tracked using end-of-run summary reports and the machine's run data files.

Additional Spectra Optia Only RBCX Procedures – Effect of Needle Gauge.

Additional laboratory procedures were conducted, in order to examine the possible effects of flow rate and needle gauge on the Spectra Optia RBCX procedure. In place of the luer lock connections used in the comparative procedures described above, needles were used to access bag of bloods (representing simulated patients) and to return red blood cells to the disposable set's waste bag. Although Spectra Optia carefully monitors and limits the inlet and return pressure in order to prevent excessive sheer, these experiments were done for completeness.

Additional Spectra Optia Only RBCX Procedures – System's Ability to Process (1) Diseased Blood from Patients with Sickle Cell Disease and (2) Stored Red Blood Cells.

There are two variables that can't be addressed in the laboratory, based on procedures conducted with fresh pools of donor blood. One is the behavior of the system, when processing blood from sickle-cell patients. While the Spectra Optia system was not expected to operate differently when processing diseased vs. normal blood, a limited number of experiments were conducted using blood removed from patients with Sickle Cell Disease. The blood was obtained from red blood cell exchange procedures completed with the COBE Spectra system. Because the blood was one day old, before it could be used in a simulated RBCX patient procedure using Spectra Optia, it was likely more fragile than fresh blood. Still, its use in this validation can be reasonably expected to reveal any major, systemic effects of processing blood from patients with diseased red blood cells, using the Spectra Optia RBCX protocol.

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Finally, although freshly donated exchange blood is strongly preferred for purposes of RBC replacement in exchange procedures, the presence of alloantibodies in patients who are multiply transfused and the need for type-matching can make this difficult. Older stored blood may be required to meet a patient's unique blood type-matching requirements and may be more fragile and sensitive to device-induced hemolysis. To address this possibility, three laboratory procedures were conducted using nearly outdated blood (at 42 days of storage) as the replacement solution. This final experiment clearly represented a "worst case" scenario, as replacement blood this old would likely never be used in a clinical RBCX procedure.

Hypothesis

The validation's over-riding hypothesis was that RBCX conducted using the Spectra Optia system would perform at least as well as RBCX conducted using the COBE Spectra Apheresis system, in a controlled and clinically relevant laboratory test paradigm.

Primary Outcome Measure

The patient's final (post-procedure) hematocrit is an important clinical endpoint for all types of RBCX procedures (exchange, depletion and depletion/exchange). Mid-run hematocrit is relevant only to Spectra Optia's combined depletion/exchange procedure and, likewise, is an important clinical endpoint. Given the clinical utility and importance of these final and mid-run hematocrit measurements, they were selected as study's two primary outcome measures and were compared across device platforms.

It is important to note that the above measurements are also surrogates for another important endpoint in exchange and depletion/exchange procedures, known as the Fraction of Cells Remaining (FCR). FCR is the percentage of defective cells (e.g., Hb S+ RBCs or parasite-infected RBCs) present at the end of the procedure, compared to those present at the procedure's start. It is not possible to measure FCR in simulated-use laboratory experiments (where clinical patients are represented by carefully constructed bags of blood), as the red blood cells in the bags of blood representing the patient do not contain any hemoglobin S and, thus, cannot be distinguished from the replaced red cells. However, as discussed above, because both the Spectra Optia and COBE Spectra devices remove all blood processed and use the same equations to control the procedure, if the specified amount of replacement blood (at the proper hematocrit) is used - then achieving the targeted final hematocrit will reflect the FCR.

Secondary Outcome Measures

The study's secondary outcome measures included the following:

- *Fluid Balance Accuracy*.
  In most cases, actual RBCX procedures are run at or near 100% fluid balance. Accordingly, 100% fluid balance was targeted in all simulated patient procedures and the actual value obtained was determined by comparing the volume of the simulated patient before and after the red blood cell exchange procedure. Fluid balance accuracy was then compared for the Spectra Optia and COBE Spectra systems.
- *Procedure Duration or "Run Time"*.

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To further demonstrate the clinical utility and convenience of the new RBCX protocol, RBCX procedure run times were compared across the two apheresis platforms.

- *Hemolysis*.
  Contact with artificial surfaces and the stresses of centrifugation and pumping can damage red cells, resulting in hemolysis. Although laboratory and clinical testing has confirmed that the Spectra Optia platform does not cause undue hemolysis during therapeutic plasma exchange procedures, aged red blood cells (sometimes used as replacement cells) and cells from patients with sickle cell disease could, theoretically, be more fragile. To rule out hemolysis under these special conditions and to completely characterize device performance, the quantity of Plasma-free Hemoglobin generated during RBCX procedures was measured using the Spectra Optia device in 6 laboratory procedures. Finally, needles were used for inlet and return access to the patient bag in a few runs to demonstrate that, as designed, maximal possible sheer (which occurs across the needles) was still below the threshold necessary for hemolysis. Hemolysis was not assessed for the COBE Spectra, and has not been reported as an adverse effect in the almost 20 years that its RBCX protocol has been in clinical use.

Safety Measures

Device malfunctions were recorded for both platforms during the comparative assessment (36 total procedures), just as they would be in an actual clinical trial. Operators were instructed to formally capture these potentially safety-related events on the study's case report forms.

Selection of Apheresis Operators

To compare RBCX performance across the two device platforms using the panel of simulated-use conditions described in Table 1, experienced CaridianBCT employees operated the COBE Spectra device, while the Spectra Optia system was operated by experienced apheresis nurses. The nurses were selected from three U. S. academic medical centers that routinely perform RBCX procedures using the COBE Spectra system. To facilitate training, only nurses from centers that currently use Spectra Optia for TPE were invited to participate. Clinical apheresis nurses, as opposed to CaridianBCT employees, were asked to run the Spectra Optia procedures, in order to confirm that the new protocol would meet their clinical needs. One nurse participated in the study from each of the following apheresis centers: 1) the University of North Carolina, Raleigh Durham, NC, 2) the University of Michigan, Ann Arbor, MI and, 3) Karmanos Cancer Institute, Detroit, MI. The nurses received a half-day of RBCX training on the Optia platform, before beginning the simulation.

Investigational Procedures

Blood and Solution Procurement

Type-matched human whole blood units from volunteer donors were purchased from (1) Interstate Blood Bank, Memphis, Tennessee, (2) Research Blood Components LLC,

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Brighton, Massachusetts or, (3) Belle Bonfils Blood Bank, Denver, Colorado. The units were drawn in ACD-A and were shipped at room temperature, either on the day of the donation or overnight.

De-identified waste red blood cells, obtained from RBCX procedures conducted on patients with sickle cell disease, were provided by the Karmanos Cancer Institute, Detroit, MI. The removed red cells were shipped overnight at room temperature and contained between 20% and 30% Hemoglobin S.

Aged packed RBCs (leukoreduced) were obtained from Bonfils Blood Center, Denver, CO, and were used on day 42 of storage.

Saline was purchased from Baxter Healthcare.

Laboratory Equipment

The following, calibrated equipment was used throughout the validation.

- Sorvall Centrifuge (Model RC3BP): *Used to concentrate blood.*
- Beckman Coulter Cell Counter System (Model ACT diff): *Used to measure starting, mid-procedure, and final hematocrits in triplicate.*
- Fenwall Plasma Expresser (Model 4R4414): *Used to remove plasma from blood products.*
- Mettler Toledo Balance (Model SB8001): *Used to measure weights of blood products.*

Blood Preparation Procedures

Whole blood was manipulated (by centrifugation or the addition of type-matched plasma) to obtain blood bags representing the "simulated patients" and appropriate replacement red blood cells, as described in Table 1.

The purchased blood units were assumed to have a hematocrit of 35%, for ease of calculations and processing. For bags (simulated patients) requiring hematocrits greater than 35%, blood units were spun down in a centrifuge for 8 minutes at 3000 RPM and 22 degrees Celsius. The calculated amount of plasma to be removed from each unit was hand expressed and the remaining blood was drained into a pre-weighed bag, until the desired volume (+/- 100 milliliters) was reached. A one milliliter sample was pulled from the bag and the hematocrit checked. If the hematocrit was within three of the hematocrit specified in Table 1, two additional samples, of one milliliter each, were drawn and the hematocrit was re-measured. If the hematocrit was not within three of the specified value, type-matched plasma was added, the bag mixed, and a one milliliter sample pulled to re-check the hematocrit. This process was repeated until the desired hematocrit (+/- 3 hematocrit units) was reached. Volume was then drained from the bag until the desired volume (+/- 100 milliliters) was obtained. For bags requiring hematocrits less than 35%, type-matched

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plasma was used to dilute the bag until the specified hematocrit (+/- 3) was reached. In some cases, blood from one procedure was re-used a second time for another procedure - with appropriate readjustment of hematocrit and volume.

All blood was used within two days of receipt and none of the blood products were tested for sickle cell trait. The replacement solutions used were not leukoreduced, except in simulated-use conditions 3 and 4 (see Table 1) and in the Spectra Optia procedures conducted using 42-day-old stored packed RBCs as the replacement solution.

Throughout the course of the comparative assessment, each simulated-use condition was assembled six independent times, from different pools of blood. Table 2 shows the actual volumes and hematocrits of the blood bags used to simulate the six replicated patient conditions and confirms that the blood bags were prepared as specified.

Table 2. Actual Volumes and Hematocrits of Panel of Simulated Patient Conditions.

Simulated Patient #	RBCX Procedure Type	Total Blood Volume	Actual Total Blood Volume		Start Hct	Actual Start Hct		% Difference Volume		% Difference Hematocrit	
		Goal	COBE Spectra	Spectra Optia	Goal	COBE Spectra	Spectra Optia	COBE Spectra	Spectra Optia	COBE Spectra	Spectra Optia
1A	exchange	1500	1450	1495	27	28.0	27.8	-3%	0%	4%	3%
1B	exchange	1500	1441	1516	27	26.8	27.3	-4%	1%	-1%	1%
1C	exchange	1500	1452	1510	27	27.4	29.8	-3%	1%	1%	10%
2A	exchange	4000	3830	3922	20	21.2	21.9	-4%	-2%	6%	9%
2B	exchange	4000	3868	3911	20	22.0	21.1	-3%	-2%	10%	6%
2C	exchange	4000	3904	3933	20	21.1	22	-2%	-2%	6%	10%
3A	dep/exch	1500	1488	1506	30	29.0	32.2	-1%	0%	-3%	7%
3B	dep/exch	1500	1777	1499	30	29.0	31.5	18%	0%	-3%	5%
3C	dep/exch	1500	1417	1507	30	27.0	30.2	-6%	0%	-10%	1%
3D	dep/exch	1500	1508	no run	30	30.6	no run	1%	no run	2%	no run
4A	dep/exch	5000	5005	4928	25	25.5	26.9	0%	-1%	2%	8%
4B	dep/exch	5000	4767	4889	25	27.3	26.1	-5%	-2%	9%	4%
4C	dep/exch	5000	4865	4859	25	25.6	26.7	-3%	-3%	2%	7%
5A	depletion	1500	1439	1450	70	70.1	69.9	-4%	-3%	0%	0%
5B	depletion	1500	1487	1459	70	72.0	69.2	-1%	-3%	3%	-1%
5C	depletion	1500	1495	1479	70	71.0	69.2	0%	-1%	1%	-1%
6A	depletion	3300	2956	3135	70	69.0	68.8	-10%	-5%	-1%	-2%
6B	depletion	3300	3014	3089	70	68.1	70.1	-9%	-6%	-3%	0%
6C	depletion	3300	3120	3130	70	69.6	72.2	-5%	-5%	-1%	3%

no run-- a fourth COBE Spectra procedure, 3D, was done because a significant operator error occurred during procedure 3C. This was not necessary for Spectra Optia.

RBCX Procedures

All Red Blood Cell Exchange procedures were performed at CaridianBCT's Lakewood facility and were conducted using the following device settings and conditions.

- **AC Infusion Rate and Inlet:AC Ratio**: COBE Spectra procedures were performed using default conditions of 0.9 mLs/min/kg for the AC infusion rate and an Inlet:AC ratio of 13. Similarly, Spectra Optia procedures were run at default conditions of 0.8 mLs/min/kg for the AC infusion rate and an Inlet:AC ratio of 13.

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- **Inlet Flow Rates**: Small total blood volume (TBV) (pediatric-type) procedures (simulated-use conditions 1, 3, and 5) were performed at 10-20 mLs/min inlet flow, while large TBV (adult-type) procedures (simulated-use conditions 2, 4, and 6) were run at 40-60 mLs/min inlet flow. These different flow rates represent known differences in the conduct of RBCX procedures for pediatric and adult patients, respectively.

- **Connections - Blood Bags to Spectra Optia and COBE Spectra Disposable Tubing Sets**: For procedures conducted to compare RBCX on the two apheresis systems, blood bags were connected to the disposable tubing sets using luer lock connections. For the additional (non-comparative) runs performed on Spectra Optia, needles were utilized for inlet and return access to the blood bag.

- **Data Entry Requirements**: Operators were instructed to enter the "patient" parameters listed in Table 1 (sex, height and weight) into the COBE Spectra or Spectra Optia user interface and to enter the simulated patient's (i.e., blood bag's) TBV, starting hematocrit (Hct), replacement volume and Hct as specified in Table 2. The targeted mid- and end-run hematocrits were entered exactly as they appear in Table 1.

Hematocrit Measurements

All hematocrit determinations were performed by CaridianBCT personnel. The measurements were made in triplicate and the average of the three was used for calculations.

Volume Measurements

For purposes of entering a TBV into the device, the tared weight was used. For all analytic calculations, volumes were determined from bag weights (tared) and hematocrits, using the following formula:

Volume (mLs)=[(bag wt(gm) x Hct) / RBC specific gravity (gm/mL)] + [(bag wt(gm) * (1-Hct))/plasma specific gravity (gm/mL)]

RBC specific gravity =1.0941, plasma specific gravity = 1.025.

Plasma Free Hemoglobin Measurements

Samples were submitted to the *Clinical Laboratory at the University of Colorado Hospital*, Aurora, Colorado, for analysis. Sample preparation (removal of RBCs) was carried out as specified by the laboratory, to minimize any artifactual generation of hemolysis. Results of the analysis were expressed as mg/dL of hemoglobin.

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Hemoglobin S Measurements

Blood samples for hemoglobin S (Hb S) measurements also were submitted to the *Clinical Laboratory at the University of Colorado Hospital*, Aurora, Colorado for analysis. Analysis results were expressed as the percentage of the total hemoglobin that was Hb S.

Statistical and Analytic Methods: Comparative RBCX Procedures

As described previously, the validation was designed as a non-inferiority study. Because both the COBE Spectra and Spectra Optia systems remove essentially all red blood cells processed and use the same underlying equations to perform the therapeutic procedure, implementation of the RBCX protocol on the Spectra Optia platform was not expected to result in a performance enhancement.

Sample Size

Sample size was estimated based on the primary outcome measure - the accuracy with which each device achieved the targeted end hematocrit.

A power analysis of a non-inferiority test of the ratio of two means was used to determine the necessary sample size using PASS 2005 Software, and is presented in Appendix 1. Using this method, the null hypothesis, H_0, was $R \geq 1+E$, where R is the ratio of the Spectra Optia mean difference/COBE Spectra mean difference. Each mean is the mean of the absolute values of the differences of the target – actual final hematocrits (measured in points). For example, for a target final Hct of 30 and an actual final Hct of 25 or 35 the difference would be 5. E is the equivalence margin. If H_0 could be rejected at $\alpha<0.025$, the alternative hypothesis, H_1, $R<1+E$ would be accepted and non-inferiority would be demonstrated.

As laboratory data on Spectra Optia RBCX performance were not available, the following assumptions were made to perform the sample size analysis. The equivalence margin was set at 10%, after consultation with a physician with extensive apheresis experience, and the coefficient of variation (CV) was estimated to be 0.1. To minimize the CV, study hematocrits were measured in triplicate and the volumes of the blood bags were determined by weight, with the appropriate scaling factors for specific gravity of the components. The results of the sample size analysis are show graphically in Figure 1.

Figure 1. Sample Size Analysis – Non-Inferiority Hypothesis

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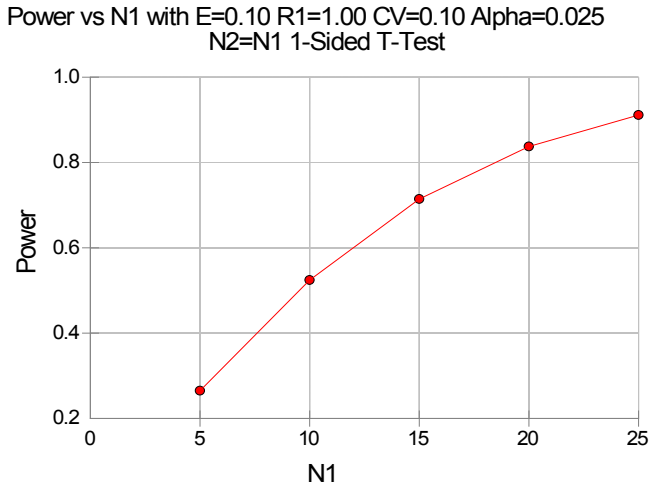

As shown above, a sample size of 18 comparative runs achieves 80% power to detect the non-inferiority of the Spectra Optia RBCX protocol (α=0.025), with an Equivalence Margin of 10% and a CV of 0.1. As designed, including the mid-run measurements in the depletion/exchange procedures, the validation study included 24 hematocrit measurements for both the COBE Spectra and Spectra Optia systems.

Analysis Methods

Independence of Measurements.
Each RBCX procedure was considered an independent measurement, as the blood bags simulating patients were individually prepared from different pools of type-matched whole human blood. Because the basic algorithms for achieving targeted hematocrit and fluid balance values are the same, regardless of whether an exchange, depletion or depletion/exchange procedure is performed, the results of all COBE Spectra/Spectra Optia RBCX procedures were analyzed together. Also included were the mid-run hematocrit accuracies for the depletion/exchange procedures, as these are achieved using the same strategy.

Hematocrit and Fluid Balance Accuracy.
Results were examined for normality using the Skewness Test and, if normality could not be rejected, a t-test was used to evaluate the null hypotheses. If normality was ruled out, a Wilcoxan Rank Sum Test of Medians was employed. Note that the null hypothesis for non-inferiority of the primary outcome measure is slightly different than for the purpose of sample size estimation (where ratios were used). For analysis, H_0 is Median Difference Optia ≥ Median Difference Spectra + 10%.

Fluid Balance Accuracy.
Fluid balance was calculated as $\frac{final\ volume\ of\ patient\ bag - initial\ volume\ of\ patient\ bag}{initial\ volume\ of\ patient\ bag}$ x 100%.

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COBE Spectra does not monitor fluid balance during the priming of the disposable. During this part of the procedure, approximately 120 mLs of blood are removed from the patient before RBC replacement begins. Mindful of this, some clinical operators will adjust the requested fluid balance on the COBE Spectra platform to make up for this deficit. To determine how well COBE Spectra maintains fluid balance subsequent to this initial period, this 120 mLs was subtracted from the initial volume of the patient blood bag, prior to calculating fluid balance accuracy. The Spectra Optia system monitors fluid balance over the entire apheresis procedure and no correction was needed.

Hemolysis (Non-comparative assessment characterizing the Spectra Optia RBCX Protocol).
If present, hemolysis was evaluated against the device specification (identical for COBE Spectra and Spectra Optia).That is, that patient plasma free hemoglobin (PFH), caused by the device, not increase more than 50mg/dL over the course of an exchange procedure. Hemolysis already present at the start of a procedure or added during the procedure, due to using pooled blood, waste blood from patients with Sickle Cell Disease, or aged RBC units did not count towards this specification.

Results

Protocol Deviations

During the course of the comparative portion of the laboratory validation, the following protocol deviations occurred. These deviations had minimal impact on the study's primary outcome measure and no Spectra Optia data were excluded from the analysis, as a result of a deviation.

1. The operator neglected to measure mid-run hematocrits on the COBE Spectra system for simulated-patient procedures #3A and #3C (see Table 1). These missing values were not imputed for purposes of analysis.

2. During COBE Spectra procedure #3C, a saline line was left unclamped - resulting in excess saline flow to the patient bag and a lower than expected final hematocrit. An additional COBE Spectra procedure (#3D) was conducted, repeating the procedure. Procedure #3C for the COBE Spectra device was excluded from the fluid balance calculation, as it was an obvious outlier of known cause and its inclusion would have distorted the overall results in favor of Spectra Optia.

3. Procedure #1B on COBE Spectra was run at an ACD-A infusion rate higher than the default, which shortened both the predicted and actual times of the procedure. This did not affect the other outcome measures and these results were included in the calculations.

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4. During Spectra Optia procedure #6B, in response to hemolysis pre-existent in the bag of pooled human blood, the operator incorrectly adjusted the target hematocrit value for the procedure and artifactually decreased the final hematocrit in the patient bag.

Device Malfunctions

No COBE Spectra or the Spectra Optia device malfunctions were observed during the comparative study, and no potential safety concerns were raised.

Primary Outcome Measure

Achievement of Targeted Hematocrit

Two of the procedures, #3C for COBE Spectra and #6B for Spectra Optia, were compromised by operator error, as noted above. Because the overall effect of the deviations was minor and did not adversely affect the final hematocrits, the results of these procedures have not been excluded from analysis.

The differences between the targeted and achieved patient hematocrits are examined for the COBE Spectra system in Table 3 and for Spectra Optia in Table 4. Results are shown for each procedure type (1 - 6) individually, with A, B, and C designating the three replications.

Table 3 Hematocrit Accuracy--COBE Spectra Runs

Simulated Patient	RBCX Procedure Type	TBV (mL)	Midrun Target	Midrun Actual	Post Target	Post Actual	**Midrun T-A Hct Points**	**Midrun (T-A)/T (%)**	**Post T-A Hct Points**	**Post (T-A)/T (%)**
1A	exchange	1450	NA	NA	30	31.0	NA	NA	1.0	3.3%
1B	exchange	1441	NA	NA	30	36.0	NA	NA	6.0	20.0%
1C	exchange	1452	NA	NA	30	31.5	NA	NA	1.5	5.0%
2A	exchange	3830	NA	NA	30	35.0	NA	NA	5.0	16.7%
2B	exchange	3868	NA	NA	30	31.0	NA	NA	1.0	3.3%
2C	exchange	3904	NA	NA	30	29.6	NA	NA	-0.4	-1.3%
3A	dep/exch	1488	24	ND	30	24.0	ND	ND	-6.0	-20.0%
3B	dep/exch	1777	24	21.0	30	27.0	3.0	12.5%	-3.0	-10.0%
3C	dep/exch	1417	24	ND	30	26.0	ND	ND	-4.0	-13.3%
3D	dep/exch	1508	24	23.7	30	31.7	0.3	1.3%	1.7	5.7%
4A	dep/exch	5005	20	19.2	35	35.4	0.8	4.0%	0.4	1.1%
4B	dep/exch	4767	20	19.0	35	34.0	1.0	5.0%	-1.0	-2.9%
4C	dep/exch	4865	20	20.0	35	36.8	0.0	0.0%	1.8	5.1%
5A	depletion	1439	NA	NA	50	50.2	NA	NA	0.2	0.4%
5B	depletion	1487	NA	NA	50	50.0	NA	NA	0.0	0.0%
5C	depletion	1495	NA	NA	50	50.0	NA	NA	0.0	0.0%
6A	depletion	2956	NA	NA	50	47.0	NA	NA	-3.0	-6.0%
6B	depletion	3014	NA	NA	50	56.0	NA	NA	6.0	12.0%
6C	depletion	3120	NA	NA	50	46.1	NA	NA	-3.9	-7.8%
median (absolute values)							**0.8**	**4.0%**	**1.5**	**5.0%**
median (absolute values) Midrun + Post Hct Points							**1.000**			
95% CI							**0.4-3.0**			

NA=not applicable ND=not done

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Table 4 Hematocrit Accuracy--Spectra Optia Runs

Simulated Patient	RBCX Procedure Type	TBV(mL)	Midrun Target	Midrun Actual	Post Target	Post Actual	**Midrun T-A Hct Points**	**Midrun (T-A)/T (%)**	**Post A-T Hct Points**	**Post (T-A)/T (%)**
1A	exchange	1495	NA	NA	30	30.0	NA	NA	0.0	0.0%
1B	exchange	1516	NA	NA	30	30.3	NA	NA	0.3	0.9%
1C	exchange	1510	NA	NA	30	29.0	NA	NA	-1.0	-3.4%
2A	exchange	3922	NA	NA	30	29.2	NA	NA	-0.8	-2.7%
2B	exchange	3911	NA	NA	30	31.1	NA	NA	1.1	3.7%
2C	exchange	3933	NA	NA	30	30.8	NA	NA	0.8	2.7%
3A	dep/exch	1506	24	23.5	30	31.3	0.5	2.1%	1.3	4.3%
3B	dep/exch	1499	24	23.1	30	29.8	0.9	3.7%	-0.2	-0.6%
3C	dep/exch	1507	24	23.1	30	29.8	0.9	3.9%	-0.2	-0.7%
4A	dep/exch	4928	20	19.5	35	34.5	0.5	2.7%	-0.5	-1.3%
4B	dep/exch	4889	20	20.3	35	36.4	-0.3	-1.6%	1.4	3.9%
4C	dep/exch	4859	20	19.6	35	36.2	0.4	1.9%	1.2	3.4%
5A	depletion	1450	NA	NA	50	49.7	NA	NA	-0.3	-0.5%
5B	depletion	1459	NA	NA	50	50.6	NA	NA	0.6	1.1%
5C	depletion	1479	NA	NA	50	49.2	NA	NA	-0.8	-1.6%
6A	depletion	3135	NA	NA	50	49.9	NA	NA	-0.1	-0.2%
6B	depletion	3089	NA	NA	50	44.3	NA	NA	-5.7	-11.5%
6C	depletion	3130	NA	NA	50	50.0	NA	NA	0.0	0.0%
median (absolute values)							**0.5**	**2.4%**	**0.7**	**1.5%**
median (absolute values) Midrun + Post Hct Points							**0.565**			
95% CI							**0.3-0.9**			

NA=not applicable

The criterion set for non-inferiority was that the average absolute difference between the targeted and the actual achieved hematocrit for Spectra Optia not exceed that for COBE Spectra, by more than 10%. As the values for both the Spectra Optia and COBE Spectra systems were not normally distributed (Skewness Test), median statistics were used to test the hypothesis H_0, Median Difference Spectra Optia$\geq$ Median D ifference COBE Spectra + 10%. Descriptive statistics and the results of the Skewness Test are presented in Table 5.

Table 5. Hematocrit Accuracy

	Target - Actual COBE Spectra	Target- Actual Spectra Optia
Mean	1.988	0.828
Std Dev	2.033	1.115
Normality Skewness Test	rejected	rejected
Median	1.000	0.565
95% CI	0.4--3.0	0.3--0.9

As the median differences for the Spectra Optia and COBE Spectra systems were 0.565 and 1.000, respectively, H_0 becomes $0.565 \geq 1.100$. The Wilcoxan Ranked Sum test for the difference in medians was employed and resulted in rejection of the null hypothesis ($p=0.0009$, $Z=-3.1171$), as shown in Table 6.

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Table 6. Significance of Hematocrit Accuracy Differences
Median Optia (T-A) ≥ Median Spectra (T-A) (+ E of 10% for non-inferiority)

H0	Test	p value	Z value
non-inferiority	Wilcoxan Ranked Sum	0.0009	-3.1171
superiority	Wilcoxan Ranked Sum	0.009	2.0658

It is readily apparent that the coefficient of variation for both COBE Spectra and Spectra Optia is much greater than 0.1, as was used in the sample size calculation. The reason that this relatively small sample yielded a significant result (despite the greater variability), most likely, is that Spectra Optia's RBCX Protocol is better at achieving the targeted hematocrit compared to COBE Spectra. This hypothesis, H_0, Median Difference Spectra Optia ≥ Median Difference COBE Spectra, is rejected at p=0.009 (Z=2.0658). Although this difference was statistically significant in this well-controlled laboratory study, it is likely that the difference may be obscured in clinical settings, due to inaccuracies in the estimation of patient TBV and measurements of patient and replace-solution hematocrits, not to mention physiologic fluid shifts and potential red cell mobilization during the procedures.

Secondary Outcome Measures

Fluid Balance

Overall fluid balance depends upon the summation of the accuracy of all pumps and, generally, is not feasible to measure clinically. This can, however, be done in a laboratory setting (such as this) where the "patient" is a bag of blood. The unique design of this study allowed an analysis of pump accuracy under simulated clinical conditions, the results of which are shown in Table 7.

The results are expressed both in terms of milliliters of extra or missing fluid, and in terms of the percentage of initial fluid present. Since the COBE Spectra system does not monitor fluid balance during the priming of the disposable, the tabled calculations account for the approximately 120 mL of fluid that is removed from the patient blood bag during this activity. This mathematical 'correction' was described in detail in a previous section.

As described in *Protocol Deviations* above, a saline line was left open during COBE Spectra procedure #3C, resulting in the free flow of saline to the patient-simulating blood bag, during the procedure. The observed fluid balance for this erroneously conducted procedure was +471mL, far in excess of any other procedure on either device. Consequently, this procedure was excluded from the fluid balance calculations.

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Table 7. Achievement of Targeted (100%) Fluid Balance

Run	Run Type	Total Blood Volume	Fluid Balance COBE Spectra					Fluid Balance Spectra Optia			
Simulated Patient	RBCX Procedure Type	Target	Final Volume	Initial Volume	Fluid Balance (mL)	Fluid Balance accounting for prime	*Corrected Fluid Balance % of initial	Final Volume	Initial volume	Fluid Balance (mL)	Fluid Balance % of initial
1A	exchange	1500	1325	1450	-124	-4	-0.3%	1515	1495	19	1.3%
1B	exchange	1500	1334	1441	-107	13	0.9%	1617	1516	101	6.7%
1C	exchange	1500	1361	1452	-91	29	2.0%	1542	1510	32	2.1%
2A	exchange	4000	3758	3830	-72	48	1.2%	3911	3922	-10	-0.3%
2B	exchange	4000	3752	3868	-116	4	0.1%	3892	3911	-19	-0.5%
2C	exchange	4000	3795	3904	-109	11	0.3%	3937	3933	4	0.1%
3A	dep/exch	1500	1371	1488	-117	3	0.2%	1471	1506	-35	-2.4%
3B	dep/exch	1500	1713	1777	-63	57	3.2%	1475	1499	-24	-1.6%
3C#	dep/exch	1500	1768	1417	351	(471)	(33.2%)	1524	1507	17	1.2%
3D	dep/exch	1501	1420	1508	-88	32	2.1%	no run	no run	no run	no run
4A	dep/exch	5000	4683	5005	-322	-202	-4.0%	4870	4928	-58	-1.2%
4B	dep/exch	5000	4591	4767	-176	-56	-1.2%	4934	4889	46	0.9%
4C	dep/exch	5000	4677	4865	-188	-68	-1.4%	4867	4859	8	0.2%
5A	depletion	1500	1337	1439	-102	18	1.2%	1427	1450	-23	-1.6%
5B	depletion	1500	1418	1487	-69	51	3.4%	1456	1459	-3	-0.2%
5C	depletion	1500	1455	1495	-40	80	5.3%	1472	1479	-6	-0.4%
6A	depletion	3300	2879	2956	-77	43	1.5%	3055	3135	-81	-2.6%
6B	depletion	3300	2889	3014	-125	-5	-0.2%	3054	3089	-34	-1.1%
6C	depletion	3300	3187	3120	66	186	6.0%	3117	3130	-14	-0.4%
Median difference (absolute value)							**1.4%**				**1.2%**
95% confidence interval							**0.3-3.2%**				**0.4-1.6%**

* corrected for the 120 mLs of fluid lost during prime/divert

#saline line not clamped for COBE Spectra run--excluded from calculation.

As for the hematocrit accuracy calculations, the absolute values of the difference between targeted (100%) and actual fluid balance are most critical and are used for all calculations. However, in Table 8, below, the ranges of actual deficit or excess fluid are also provided. Importantly, both devices yielded both negative and positive fluid balance - as is to be expected from random rather than systematic pump accuracy deviations.

Table 8. Fluid Balance Accuracy

	COBE Spectra	Spectra Optia
Mean	3.563	1.536
Std Dev	7.382	3.621
Normality Skewness	rejected	rejected
Median	1.4	1.15
95 % CI %	0.3 to 3.2	0.4 to 1.6
range %	-4% to + 6%	-2.4% to +6.7 %
range mL	-202 TO + 156	-58 to +101

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The values for percent fluid balance for both devices were not normally distributed (Skewness Test). Consequently, median statistics were used to evaluate the differences. The differences observed, 1.40% and 1.15% for the COBE Spectra and Spectra Optia systems, respectively, were not significant as evaluated by the Wilcoxan Rank Sum Test of medians (p=0.3076, Z=-1.020).

Characterization of Spectra Optia RBCX Performance: Waste Blood

All of the type-matched human blood used in the comparative runs described in Tables 3, 4 and 7 above was donated normal human blood, used within two days of being drawn. To confirm that the Spectra Optia system would perform as expected with blood from patients with diseased red blood cells. De-identified blood, removed during actual RBCX procedures, was used as the "simulated patient" in three Spectra Optia-only procedures. One procedure of each type (exchange, depletion/exchange, and depletion) was conducted. For the exchange and depletion exchange procedures, donated type-matched human blood served as the replacement solution. As shown in Table 9, hematocrit and fluid balance targets are in line with those observed in procedures using normal human blood and confirm that RBCs from patients with Sickle Cell Disease behave as expected in the Spectra Optia device.

Table 9. Optia Performance with Waste Sickle Cell Replacement Blood

Run	Run Type	Total Blood Volume		Hematocrit					Fluid Balance	
Simulated Patient	RBCX Procedure Type	Initial	Final	Initial	Mid Target	Mid Actual	Final Target	Final Actual	Target	Actual
1	exchange SC blood	2678	2662	44.9	NA	NA	43	42.6	100%	99%
2	dep/exch SC Blood	1141	1121	48.3	38	36.6	42	39.5	100%	98%
3	depletion SC Blood	1321	1322	48.6	NA	NA	29	27.1	100%	100%
4	exchange with 42 day old replace	1640	1500	31.7	NA	NA	40	39.7	100%	100%

NA, not applicable

Characterization of Spectra Optia RBCX Performance: Hemolysis

Contact with artificial surfaces and the stresses of centrifugation and pumping can damage red cells, resulting in hemolysis. Although laboratory and clinical testing has confirmed that the Spectra Optia platform does not cause undue hemolysis during therapeutic plasma exchange procedures, aged red blood cells (sometimes used as replacement cells) and cells from patients with sickle cell disease could, theoretically, be more fragile and susceptible to hemolysis. Finally, low TBV procedures are more commonly conducted in RBCX, compared to TPE. These low TBV procedures may require smaller needle sizes that, in turn, result in greater shear forces than commonly seen in TPE – and hemolysis. To rule out hemolysis under these special conditions and to completely characterize device performance, the quantity of Plasma-free Hemoglobin generated during RBCX procedures was measured for the Spectra Optia RBCX in the following laboratory procedures.

Evaluation of Hemolysis using Waste Blood from Patients with Sickle Cell Disease.

The three procedures described above in Table 9 were also examined for the generation of plasma free hemoglobin. In these procedures, the day-old RBCs were expected to be even

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more fragile than blood obtained in real-time from sickle cell patients. The results of the analysis are shown in Table 10. Also shown are data on the target and actual FCR, which, as mentioned above could not be measured in procedures using donated normal blood. Since waste blood from clinical RBCX procedures on sickle cell patients does contain some RBCs with Hb S, the fraction of HbS (FCR) remaining in the "patient bag" after the procedure could be compared with the fraction of HbS present before the procedure.

Table 10. FCR and Plasma Free Hemoglobin in Optia RBCX

Simulated Patient	RBCX Procedure Type	Fraction of Cells Remaining		Plasma Free Hemoglobin	
		Target	Actual	Total increase (mg)	increase in Pt (mg/dL)
1	exchange SC blood	58	52	152	4.7
2	dep/exch SC Blood	65	71	-175	-53.3
3	depletion SC Blood	100	103	-327	-95

NA, not applicable
*Of the 54mg/dL increase in the "patient", approximately 60% came from the preexistant hemolysis in the aged blood which contained an average of 87mg/dL.

In Procedure 1, a total increase, in the "simulated patient bag" and in the removed blood bag, of 152 mg of PFH was present and led to a trivial increase in the simulated patient's plasma of 4.7 mg/dL. This increase is in the background of the assay, as values below 10-20 mg/dL are of questionable significance, and often result just from the handling of the cells during testing. Procedures 2 and 3 actually show a decrease in the total amount of PFH over the course of the procedure. This, most likely, reflects the variance inherent in the assay. Procedures 2 and 3 were completed with a split pool of the same RBCX waste product and should have had the same level of PFH at the start of the procedure; however, these values were 176 and 121 mg/dL, respectively. Thus, it seems fair to conclude that little, if any, hemolysis was observed in these runs using waste RBCs from sickle cell patients.

The use of waste blood from patients with sickle cell disease also made it possible to assay for the percentage of Hemoglobin S in the blood bags, before and after the procedure. Unlike the laboratory procedures conducted with type-matched pooled donor blood, this allowed a direct comparison of the target and actual Fraction of Cells Remaining (FCR) (see Table 10). The "target" FCR is input into Spectra Optia as a goal of the procedure, while the "actual" FCR is simply the percentage of Hemoglobin S still present at the end of the procedure, divided by the percentage present at the start of the procedure. The fact that the actual values are both above and below the targets reflects the variability in the assay.

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Evaluation of Hemolysis as a Function of Needle Gauge and Flow Rate.
An experimental procedure was designed to investigate the effects of needle gauge and flow rate on hemolysis, using the Spectra Optia RBCX protocol. The procedure was divided into four phases, with each phase running for 15 minutes utilizing specified-gauge needles for inlet and return access to the blood bag and specified flow rates. The volume of the patient blood bag used in the experiment was 3500 mL.

As shown in Table 11, the increase in plasma free hemoglobin (PFH) in the blood bag increased from 3.6 to 5.8 mg/dL over the course of the experiment, indicating that very little hemolysis occurred. The increase in PFH/liter of inlet processed ranged from 0.8 to 1.6 mg/dL and did not correlate with increasing flow rate or needle gauge. This validates the Spectra Optia's design requirement that all possible combinations of needle gauge and flow rates remain below the shear threshold necessary to cause hemolysis. For example, a flow rate of 60 mL/min could not be achieved with a 20 gauge needle, as this led to excessive return pressure - which is monitored and prevented by the device. Even at the highest rate of hemolysis observed, 1.6mg PFH increase/ L of inlet processed, over 31 liters of inlet would need to be processed to exceed the specification of no more than a 50 mg/dL increase in PFH over the course of the procedure. Typical RBCX procedures involve processing 1-2 TBV and would never approach 30 liters of inlet volume processed.

Table 11. Effect of Needle Size and Flow Rate on Hemolysis

Needle gauge	Inlet Flow Rate (ml/min)	Inlet Volume Processed (mL)	PFH pre (mg/dL)	PFH post (mg/dL)	PFH increase (mg/dL)	PFH increase/L processed (mg/dL)
18	80	1200	2.7	3.6	0.9	0.8
18	50	750	3.6	4.8	1.2	1.6
18	20	300	4.8	5.2	0.4	1.3
20	30	450	5.2	5.8	0.6	1.3

Evaluation of Hemolysis Using 42-Day-Old Stored Blood as Replacement Solution.
Two RBCX exchange procedures were performed using Spectra Optia to examine the risk of hemolysis, using 42-day-old stored blood as a replacement fluid. This represents a worst-case scenario, as replacement blood is typically requested to be as fresh as possible in order to maximize the length of RBC survival in vivo. Each of the two procedures was a 4-unit exchange in a "simulated patient" with a TBV of about 2200 mL. Such an exchange would allow an FCR of about 35%, which is typical of routine RBCX procedures. To detect and quantify any hemolysis that occurred during the procedure, the simulated patient, replace and remove bags were weighed and sampled before and after each replacement unit was processed. Samples were prepared and sent for plasma free hemoglobin (PFH) determinations at each of these points. In this way, it was possible to track the total amount of PFH present at each point and to determine how much was pre-existent in the pooled

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human blood that comprised the patient bag, how much was pre-existent in the aged replacement units and entered the system as the replace units were added, and how much occurred during the procedure itself. The data for the first procedure are presented in Table 12 and for the second procedure in Table 13.

Table 12. Hemolysis when using 42 day old Replace Blood--Procedure 1

	Patient Bag			Replace Bag			Remove Bag			Total PFH
Stage of Exchange	Vol (mL)	PFH (mg/dL)	PFH (mg)	Vol (mL)	PFH (mg/dL)	PFH (mg)	Vol (mL)	PFH* (mg/dL)	PFH* (mg)	PFH (mg)
Start First Aged Unit	2215	**2.0**	44.3	281	131.8	370.4				414.7
End First Aged Unit	2190	**15.3**	335.1				415	16.7	69.305	404.4
PFH generated										**-10.3**
Max increase in pt due to procedure		-0.5								
Start Second Aged Unit	2190	**15.3**	335.1	282	113.4	319.8				654.9
End Second Aged Unit	2184	**24.3**	530.7				311	47.2	273.7	804.4
PFH generated										**149.6**
Max increase in pt due to procedure		6.8								
Start Third Aged Unit	2184	**24.3**	530.7	310	65.0	201.5				732.2
End Third Aged Unit	2193	**29.3**	642.5				342	34.6	26.5	669.0
PFH generated										**-63.2**
Max increase in pt due to procedure		-2.9								
Start Forth Aged Unit	2193	**29.3**	642.5	218	60.8	132.5				775.1
End Forth Aged Unit	2194	**30.9**	677.9				238	55.9	360.5	1038.4
PFH generated										**263.4**
Max increase in pt due to procedure		12.0								

At the start of the first experiment, the patient bag contained a negligible concentration of PFH of 2.0 mg/dL for a total amount of 44.3 mg. This value is typical of what would be expected in an actual patient. As the exchange proceeded, the first replacement unit was given to the simulated patient, along with the 370.4 mg of PFH that it contained. Because determining how much of the replace PFH remains in the patient bag and how much is removed is difficult, the amount of PFH generated during the procedure is calculated by subtracting the initial amount of PFH present in the patient and replace bags (414.7 mg) from the amount present in the patient bag and the remove bag after each replace unit has been added (404.4 mg). Thus, during the exchange of the first unit of 42-day-old replacement blood, there appears to have been a net decrease of 10.3 mg of total PFH, implying that no hemolysis occurred and that the increase in the patient bag from 2.0 to 15.3 mg/dL is solely due to the addition of PFH from the replacement unit. The exchange of the second unit resulted in 140.6 mg of additional PFH. If all of this remained in the patient, it would raise the PFH concentration by 6.8mg/dL. Looking at the entire 4 unit exchange, the PFH concentration in the patient bag increased from 2 to 30.9 mg/dL. Of this, only about 19 mg/dL could have occurred due to hemolysis generated during the procedure.

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Table 13. Hemolysis when using 42 day old Replace Blood--Procedure 2

	Patient Bag			Replace Bag			Remove Bag			Total PFH
Stage of Exchange	Vol (mL)	PFH (mg/dL)	PFH (mg)	Vol (mL)	PFH (mg/dL)	PFH (mg)	Vol (mL)	PFH* (mg/dL)	PFH* (mg)	PFH (mg)
Start First Aged Unit	2175	**5.9**	128.3	267	46.9	125.2				253.5
End First Aged Unit	2161	**12.0**	259.3				392	14.6	57.232	316.6
PFH generated										**63.0**
Max increase in pt due to procedure		2.9								
Start Second Aged Unit	2161	**12.0**	259.3	294	120.9	355.4				614.8
End Second Aged Unit	2162	**26.8**	579.4				313	24	111.8	691.2
PFH generated										**76.4**
Max increase in pt due to procedure		3.5								
Start Third Aged Unit	2162	**26.8**	579.4	274	88.0	241.1				820.5
End Third Aged Unit	2170	**29.2**	633.6				298	54.5	377.6	1011.2
PFH generated										**190.7**
Max increase in pt due to procedure		8.8								
Start Forth Aged Unit	2170	**29.2**	633.6	252	113.9	287.0				920.7
End Forth Aged Unit	2172	**37.3**	810.2				268	59.5	209.6	1019.8
PFH generated										**99.1**
Max increase in pt due to procedure		4.6								

Similarly for second experiment, the increase of PFH in the patient bag was from 5.9 to 37.3 mg/dL, of which only 19.7 mg/dL could be attributable to hemolysis caused by the device. The actual increase due to device-caused hemolysis will be significantly less than this, as not all of the PFH added from the replace bag will remain in the patient bag. In any case, even the maximum increase of about 19 mg/dL is well under the specification of no more than 50 mg/dL per procedure. More than 4-unit exchanges are done, but typically in larger patients where the goal of achieving an FCR of 30-40% remains the same.

Comparison of COBE Spectra and Spectra Optia RBCX Protocols: Procedure Time

Procedure times are shown in Table 14. Values for COBE Spectra procedure 1B and Spectra Optia procedure 6B were judged to be unreliable. In the first case, the run was accidentally carried out using an AC infusion rate higher than the default. In the latter case, the presence of hemolysis in the patient bag led to a number of alarms and pauses.

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Table 14. Procedure Times

Run	Run Type	Total Blood Volume	COBE Spectra		Spectra Optia	
		Target	Predicted	Actual	Predicted	Actual
1A	exchange	1500	139	140	137	135
1B	exchange	1500	115*	116*	141	131
1C	exchange	1500	131	131	141	140
2A	exchange	4000	64	64	60	59
2B	exchange	4000	64	64	58	57
2C	exchange	4000	53	53	59	58
3A	dep/exch	1500	129	129	110	113
3B	dep/exch	1500	86	97	111	113
3C	dep/exch	1500	109	106	105	107
3D	dep/exch	1500	117	117	no run	no run
4A	dep/exch	5000	NR	76	75	74
4B	dep/exch	5000	87	85	70	70
4C	dep/exch	5000	84	84	76	76
5A	depletion	1500	37	37	27	25
5B	depletion	1500	39	NR	27	36
5C	depletion	1500	38	38	28	33
6A	depletion	3300	33	NR	27	31
6B	depletion	3300	31	31	27	71#
6C	depletion	3300	34	34	28	33

* this run was accidentally run at a higher AC infusion rate

this run was complicated by preexistant hemolysis in the Patient bag

NR, inadvertantly not recorded

no run--a 4th procedure, 3D, was run on COBE Spectra (only) because or a technical error during the 3rd procedure on this device.

Table 15 presents the average RBCX procedure times for the two device platforms - excluding runs 1B and 6B. For both devices, the predicted times are very close to the actual times, and the differences between the two devices are insignificant. It should be noted that these runs were not conducted using needles and it is likely that, as for TPE, when the flow rate is limited by inlet or return access pressure, COBE Spectra will run about 8% faster, due to the intermittent return of fluid employed by Spectra Optia.

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Table 15. Average Procedure Times

RBCX Procedure Type	COBE Spectra		Spectra Optia	
	Predicted	Actual	Predicted	Actual
Low TBV	135	136	140	135
High TBV	60	60	59	58
Low TBV	110	112	109	111
High TBV	86	84	74	73
Low TBV	38	37	27	31
High TBV	32	31	27	32

Conclusions

The principal findings of this study are summarized in Table 16.

Table 16. Summary of Principal Findings

		COBE Spectra	Spectra Optia
Primary Outcome Measure Hematocrit Accuracy (Target-Actual Hct units)	Median difference 95% confidence	1 0.4 to 3.0	0.56 0.3 to 0.9
Secondary Outcome Measure Fluid Balance (Target-Actual %)	Median difference 95% confidence	1.4 0.3 to 3.2	1.2 0.4 to 1.6

With respect to the primary outcome measure, Spectra Optia easily demonstrated non-inferior performance of the RBCX procedure when compared with that of the precedent COBE Spectra device. In fact, in this laboratory study, Spectra Optia achieved the targeted patient hematocrit more accurately than did the COBE Spectra.

With respect to the secondary outcome measure of fluid balance accuracy, Spectra Optia demonstrated equivalent accuracy in achieving the targeted fluid balance.

Procedure times are very similar for the two devices, but Spectra Optia is expected to be slightly slower (about 8%) in situations where COBE Spectra is run at the maximum flow rate possible. This difference is not expected to be clinically significant.

Confirmatory experiments run on Spectra Optia did not reveal any unexpected behavior. Experiments using Sickle Cell waste blood as the simulated patient demonstrated that Spectra Optia's RBCX protocol processed this blood normally and did not induce undue hemolysis. Similarly, experiments using 42-day-old stored blood as replacement fluid demonstrated that Spectra Optia did not induce undue hemolysis even for compromised RBCs. Finally, under achievable conditions, small needle size and high flow rate did not lead to significant hemolysis.

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In conclusion, the performance of the Spectra Optia RBCX Protocol is functionally equivalent to that of the precedent COBE Spectra device and is ready for clinical use.

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Appendix 1

Power Analysis of a Non-Inferiority Test of The Ratio of Two Means

Numeric Results for Non-Inferiority Test (H0: R >= 1+E; H1: R < 1+E)
Test Statistic: T-Test

Power	N1/N2	Equivalence Margin (E)	Equivalence Bound (RB)	True Ratio (R1)	Significance Level (Alpha)	Coefficient of Variation (COV)	Beta
0.2653	5/5	0.10	1.10	1.00	0.0250	0.10	0.7347
0.5247	10/10	0.10	1.10	1.00	0.0250	0.10	0.4753
0.7143	15/15	0.10	1.10	1.00	0.0250	0.10	0.2857
0.8375	20/20	0.10	1.10	1.00	0.0250	0.10	0.1625
0.9115	25/25	0.10	1.10	1.00	0.0250	0.10	0.0885

References
Chow, S.C.; Shao, J.; Wang, H. 2003. Sample Size Calculations in Clinical Research. Marcel Dekker. New York.
Julious, Steven A. 2004. 'Tutorial in Biostatistics. Sample sizes for clinical trials with Normal data.' Statistics in Medicine, 23:1921-1986.

Report Definitions
H0 (null hypothesis) is that R >= 1+E, where R = Treatment Mean / Reference Mean.
H1 (alternative hypothesis) is that R < 1+E.
Power is the probability of rejecting H0 when it is false.
N1 is the number of subjects in the first (treatment) group.
N2 is the number of subjects in the second (reference) group.
E is the magnitude of the relative margin of equivalence.
RB is equivalence bound for the ratio.
R1 is the mean ratio (treatment/reference) at which the power is computed.
COV is the coefficient of variation on the original scale.
Alpha is the probability of falsely rejecting H0.
Beta is the probability of not rejecting H0 when it is false.

Summary Statements
Group sample sizes of 5 in the first group and 5 in the second group achieve 27% power to detect non-inferiority using a one-sided, two-sample t-test. The margin of equivalence is 0.10. The true ratio of the means at which the power is evaluated is 1.00. The significance level (alpha) of the test is 0.0250. The coefficients of variation of both groups are assumed to be 0.10.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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19 Performance Testing - Animal

Due to the nature of the device, animal performance test results are not need as support of substantial equivalence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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20 Performance Testing – Clinical

20.1 Study Design

A prospective, multicenter, single-arm, open-label study, herein referenced as ESSENTIAL: Evaluation of the Spectra Optia Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease, was conducted under IDE #G120048 to evaluate the performance of the Spectra Optia system red blood cell exchange (RBCx) protocols (exchange and depletion/exchange) in study participants with sickle cell disease.

The primary endpoint of the study was to determine the mean ratio defined by the actual fraction of cells remaining (FCRa; as measured by Post-Procedure % [HbS]) to the predicted fraction of cells remaining (FCRp; as predicted by the Spectra Optia system FCR algorithm multiplied by the measured pre-procedure %HbS), in the Evaluable Population.

The calculation of the primary endpoint is as follows:

FCRa = measured post-procedure %HbS

FCRp = Predicted (Optia) post-procedure FCR multiplied by the measured pre-procedure %HbS

If FCRa= 10.8%, and FCRp= 33% X 36.7%, then

FCRa/FCRp= 0.89

Fraction of Cells Remaining (FCR) refers to the percentage of the patients original RBCs remaining intravascularly at the end of the procedure. The *Predicted Fraction of Cells Remaining* or "*FCRp*" refers to the output of the Spectra Optia system's mathematical algorithm. A copy of the Clinical Investigation Report (CIR) is provided in **Attachment 20.1** and the Statistical Analysis Plan (SAP) is provided in **Attachment 20.2**.

20.2 Adverse Events

No serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) were reported.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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20.3 Study Results

The ratio of actual to predicted fraction of cells remaining following the RBCx procedure (0.92,) was well within the pre-specified boundaries. The tightness of the 95% CI (0.883, 0.963) indicates that the system functioned well. When these data were analyzed by type of procedure and age group, the results were consistent with the overall evaluable population.

All secondary endpoints were met as well. The procedural success rate was 100%. The Spectra Optia System was able to achieve the desired final Hct in the evaluable population (mean Hct = 1.03, median = 1.02). The investigator satisfaction rate was 100%.

20.4 Conclusions

With the primary endpoint being met with a 95% CI, favorable safety profile, and 100% investigator satisfaction, it is evident that the Red Blood Cell Exchange protocol for the Spectra Optia system is safe and effective for its proposed intended use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 20.1

Clinical Investigation Report (CIR)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Investigation Report: CFR-5001

1 TITLE PAGE

Study Title:	Evaluation of the Spectra Optia® Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease
Protocol Number:	CTS-5001
Development Phase:	Pivotal
Study Design:	Prospective, open-label, single-arm, multi-center
Investigational Device:	Spectra Optia Apheresis System
First Patient Enrolled:	07 Nov 2012
Data Base Cut-off:	21 Jun 2013
Sponsor:	Terumo BCT, Inc. 10811 W. Collins Ave. Lakewood, CO 80215 (303) 231-4986
Sponsor Contact:	(b) (6) [redacted]
Coordinating Investigator:	
Principal Investigators:	Multicenter
Final Date:	25 Jul 2013

This study was conducted in accordance with Good Clinical Practices (GCP), including the archiving of essential documents.

Confidentiality Statement

The information contained herein is confidential and the proprietary property of Terumo BCT, Inc. Any unauthorized use or disclosure of such information without the prior written authorization of Terumo BCT, Inc. is expressly prohibited.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 SYNOPSIS

Sponsor Terumo BCT, Inc.
Name of Finished Product Spectra Optia Apheresis System – Red Blood Cell Exchange protocol
Study Title Evaluation of the Spectra Optia® Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease
Protocol Number: CTS-5001
Investigator(s): Coordinating investigator = (b) (6) [redacted]
Study Center(s): multicenter study
Study Period 07 Nov 2012 to 21 Jun 2012
Purpose of the Study: To provide data to demonstrate that the Spectra Optia Apheresis System performs as designed for red blood cell exchange (RBCx) transfusion.
Objective The objective of the study was to evaluate the performance of the Spectra Optia System RBCx protocols (exchange and depletion/exchange) in study participants with sickle cell disease (SCD).
Methodology The study was a prospective, multi-center, single-arm, open-label study design. The planned enrollment was to included approximately 60 patients comprising the evaluable population (40 adults and 20 children). The intended patient population was to have SCD and to have an RBCx or RBC depletion/exchange procedure either as part of a chronic program or as a single procedure. The type of treatment procedure (RBCx or RBC depletion/exchange) was based on the investigator's recommendation. Interim analyses were conducted after 20 and 40 evaluable patients had completed the procedure to determine if the observed variability of the ratio of the fraction of actual cells remaining (FCRa) / predicted fraction of cells remaining (FCRp) is consistent with the planning estimates. An additional lead-in phase was conducted at each site to train operators on the use of the device for these procedures.
Number of Patients (Planned and Analyzed) It was anticipated that up to 72 patients may be needed to be enrolled in order to obtain 60 patients in the evaluable population and up to a maximum of another 20 patients enrolled as part of the lead-in phase. Therefore, the total projected enrollment was a maximum of 92 patients. A total of 73 patients were enrolled. One patient was found to be ineligible and

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was not treated or included in the full analysis set. The evaluable population was comprised of 60 patients. The full analysis set included the 60 patients from the evaluable population and 12 lead-in patients for a total of 72 patients.
Diagnosis and Main Criteria for Inclusion Patients had to give informed consent (IC) or assent, be ≥ 12 years old and have SCD with a need for an RBCx procedure. Patients had to have sufficient venous access for the procedure and be able to commit to the follow-up schedule.
Test Product, Device Spectra Optia Apheresis System
Duration of Treatment Patients underwent either 1 RBCx or exchange/depletion procedure and had 1 follow-up assessment within 18-24 hours post-procedure.
Criteria for Evaluation A patient was considered evaluable if he/she signed an IC/assent form, met eligibility criteria, were exposed to the study treatment, and for whom endpoint data were available without endpoint-affecting data entry errors that could not be resolved retrospectively. Lead-in patients were not included in the evaluable population but were included in the full analysis set. Safety analyses were conducted on the full analysis set.
Statistical Methods Statistical outputs are descriptive. The primary efficacy endpoint was to determine the mean ratio defined by the FCRa to the FCRp in the evaluable population. Secondary endpoints included the following: procedural success of the Spectra Optia System in the evaluable population; the ability of the Spectra Optia System to achieve the desired final hematocrit (Hct) in the evaluable population; investigator satisfaction with the device and outcome of the procedure in the evaluable population; and device-related serious adverse events (SAEs) in the full analysis set.
Summary of Results The efficacy analyses were conducted on data from all evaluable patients (n = 60). Twelve lead-in patients were enrolled but not included in the evaluable population; these patients are included in the full analysis set (n = 72). The ratio of actual to predicted fraction of cells remaining following the RBCx procedure (0.92,) was well within the pre-specified boundaries. The tightness of the 95% CI (0.883, 0.963) indicates that the system functioned well. When these data were analyzed by type of procedure and age group, the results were consistent with the overall evaluable population. All secondary endpoints were met as well. The procedural success rate was 100%. The Spectra Optia System was able to achieve the desired final Hct in the evaluable population (mean Hct = 1.03, median = 1.02). The investigator satisfaction rate was 100%. The safety profile was favorable in this study. Thirteen patients (18.1%; 95% CI: 10.0%, 28.9%) experienced at least 1 adverse event (AE). The most frequently reported AEs regardless of causality were dizziness (n = 6, 8.3%), nausea (n = 4, 5.6%), and platelet count

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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decreased (n = 4, 5.6%). All events were mild (Grade 1, n = 7, 9.7%) to moderate (Grade 2, n = 6, 8.3%) in severity. The only AEs considered related to the study device were 3 (4.2%) instances of platelet count decreased. Twelve of the 13 patients with AEs had events considered related to the study procedure. No patients had an SAE, unanticipated adverse drug effect (UADE), or withdrew from the procedure or treatment due to an AE.

Conclusions

The primary endpoint of the study was met. The ratio of actual to predicted fraction of cells remaining following the RBCx procedure (0.92,) was well within the pre-specified boundaries. The tightness of the 95% CI (0.883, 0.963) indicates that the system is functioning well. All secondary efficacy endpoints were met as well: 1) the procedural success rate was 100%; 2) the Spectra Optia System was able to achieve the desired final Hct in the evaluable population (mean Hct = 1.03, median = 1.02); and the investigator satisfaction rate was 100%.

The safety profile was favorable. Overall, 18.1% of patients experienced at least 1 AE regardless of causality; however, all events were mild to moderate in severity. The only AEs considered related to the study device were 3 instances of platelet count decrease and none required a platelet transfusion. No patients had an SAE, UADE, or withdrew from the procedure or treatment due to an AE.

Final Date: 25 Jul 2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Clinical Investigation Report

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Appendix 20.2

Statistical Analysis Plan (SAP)

NOTE: Supplemental documents available upon request

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Analysis Plan

(b)(4) Analysis Plan

(b)(4) Analysis Plan

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COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Gema Gonzalez

Subject: 510(k) Number K132429/S001

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)		X
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?	X	
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)	X	
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)	X	
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)	X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:

Class: Unclassified

Product Code: LKN

Additional Product Codes:

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	David A. Pudwill -S Acting for CYN 2013.12.06 16:58:12 -05'00'
Division Sign-Off	Benjamin R. Fisher -S 2013.12.09 20:02:37 -05'00'

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TERUMOBCT

K132429/S001

November 1, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
NOV 04 2013
Received

RE: Telephone Hold – K132429
Spectra Optia® Apheresis System - Red Blood Cell Exchange (RBCx)

Dear Sir or Madam:

In response to your October 8, 2013 email telephone hold notification related to the aforementioned submission, please find enclosed our responses to questions addressed in the email notification.

For your convenience, the original email notification questions are presented in ***bold italics***, followed by the response in unformatted text.

Terumo BCT is providing an eCopy of this submission, which is an exact duplicate of the paper copy.

Should you have any questions or require further information, please contact me at (303) 239-2082 or via email at tina.obrien@terumobct.com.

Sincerely,

Tina O'Brien

Tina O'Brien
Sr. Regulatory Affairs Specialist

Submission: 1 Original, 2 eCopies

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18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

November 1, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Telephone Hold – K132429
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Dear Sir or Madam:

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For your convenience, the original email notification questions are presented in ***bold italics***, followed by the response in unformatted text.

Terumo BCT is providing an eCopy of this submission, which is an exact duplicate of the paper copy.

Should you have any questions or require further information, please contact me at (303) 239-2082 or via email at tina.obrien@terumobct.com.

Sincerely,

Tina O'Brien

Tina O'Brien
Sr. Regulatory Affairs Specialist

Submission: 1 Original, 2 eCopies

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. In your submission, you describe three patients whose post-procedure platelet counts were said to be low and related to the study device. These events occurred at the same medical center, presumably using the same protocol. Also, you note that a total of 49 patients (68%) had a decrease in platelet counts, including 17 patients (24%) who had normal or high counts pre-procedure and decreased to low counts by their post-procedure assessment. Please provide individual data points on these patients to determine how low the platelet counts were and how soon they returned to baseline. This information is necessary to complete our review and might need to be described in your device labeling.

In the Clinical Investigation Report, only platelet counts that decreased from one reference range (High, Normal, Low), according to the local laboratory reference range, to a lower range were considered to have decreased as a result of the procedure. However, as described in Warning #2 of the RBCx *Procedure Guide* "Platelets are removed with Red Blood Cells during an RBCX procedure. The approximate percent of Platelets removed depends on the number of total blood volumes (TBV) processed, as shown in the table below. It is the physician's responsibility to determine the appropriate treatment for the patient."

As per the Clinical Investigation Protocol, the complete blood count, from which the platelet count was obtained, was collected during the post-procedure time point only. As such "return to baseline" platelet counts were not collected.

With respect to the degree of expected platelet loss, this depends on the number of total blood volumes (TBV) processed and, as RBCx procedures typically process about one TBV, the approximate expected average loss is 63%. Thus whether or not a given patient's platelet count falls from one reference range to the next lower reference range depends on how close the pre-procedure count was to the reference range lower limit and the number of TBVs processed and does not reflect any problems with the procedure. Not included in this estimate is any intra-procedure platelet production/mobilization, which can result in less than expected platelet loss.

Consequently, as requested, we have provided a table of pre-procedure and post-procedure platelet counts for all procedures (**Table 1**). The 49 patients that had a decrease in platelet count are listed first and are highlighted in Yellow or **Red**. Red highlights indicate the three patients whose platelet decrease was considered an adverse event (AE) related to the device by the Investigator. The platelet count prior to their subsequent RBCX procedure was provided by the site as part of their AE report. The count before the subsequent procedure was very close to that before the study procedure, suggesting that this is the baseline for these patients. This table also gives the expected platelet decrease depending on the number of TBVs processed and the observed platelets decrease. Expected and observed platelet decreases were calculated using the formulas:

$$\text{Expected platelet decrease} = (1-(\exp^{-\text{TBV processed}}))*100\%$$

$$\text{Observed platelet decrease} = (PLT_{pre}-PLT_{post})/PLT_{pre}*100\%$$

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TERUMOBCT

Spectra Optia® Apheresis System
K132429
Red Blood Cell Exchange (RBCx)

(b)(4) Review

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-9839; Released by CDRH on 12-8-2015

TERUMOBCT

Spectra Optia® Apheresis System
K132429
Red Blood Cell Exchange (RBCx)

(b)(4) Review

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Review

[redacted]

2. In the clinical study synopsis provided in your Clinical Investigation Report (page 2 of 58 of Section 20.1 of the current submission), you state that the study period for your clinical trial was "07 Nov 2012 to 21 June 2012." This is not consistent with the period given on page 34 of 58 of Section 20.1, where you note that patients were enrolled between November of 2012 and May of 2013. Please resolve this discrepancy and confirm the enrollment dates for your study.

The Study Period on Page 2 of the Clinical Investigation Report has been updated from "07 Nov 2012 to 21 June 2012" to "07 Nov 2012 to 21 June 2013", reflecting the duration of the entire study. A copy of the updated Clinical Investigation Report is provided in **Attachment A**. Please note that the dates referenced on Page 34 reflect the enrollment period of the study (Nov. 2012 – May 2013) only. The month of June involved data cleaning and lock.

3. As part of your clinical study, you had a lead-in phase at each investigational site to train operators on the use of your device for the proposed RBCx procedures. Please provide any available data obtained from these lead-in patients, including any information you might have on device problems or patient adverse events that may have occurred.

Safety data for both lead-in patients and evaluable patients is summarized in the Clinical Investigation Report in Section 12, Safety Evaluation. This data includes at least one (1) adverse event for three lead-in patients, as summarized in **Table 2** below. The full data set for these adverse events is provided in **Attachment B**.

Table 2: Lead-In Patient AEs

Subject ID	AE(s) Experienced
03-503	Hypercoagulation
05-502	Injection site bleeding Pain injection site
04-501	Lightheadedness, Nausea, Hypotension, Fainting, Dizziness, Lightheadedness

Section 11.4.1.2 of the Clinical Investigation Report (Page 45) details the device deficiencies, one of which occurred during a lead-in patient procedure (05-502) involving a problem with the reservoir sensor alarm. The procedure had to be aborted and was not completed, however it was determined by the Principal Investigator that the adverse event was not device related.

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4. While you listed your device's intended use in the 510(k) Summary provided in the current submission (Section 5), you did not include its indications for use, as provided in the Indications for Use statement from Section 4 of the 510(k). Please also include this Indications for Use statement (e.g., same wording), to ensure consistency across these two documents.

The 510(k) Summary has been updated to include the Indications for Use statement provided in Section 4 of the original submission. A copy of the updated 510(k) Summary is provided in **Attachment C.**

5. Please address the following deficiencies concerning the device labeling proposed in the current submission: RBCx Procedure Guide (Attachment 13.1):

a. In your RBCx Procedure Guide (Attachment 13.1), you include your device's intended use, as well as its indications for use regarding the proposed RBCx procedures. To ensure consistency across the various device labeling items, please also include these statements (e.g., same wording) in the Spectra Optia® Essentials Guide (Attachment 13.2) and the Instructions for Use for the Spectra Optia® Exchange Set (Attachment 13.3).

As noted in the Preface (Page 2) of the Spectra Optia *Essentials Guide*, "This guide is one of several guides that comprise the Spectra Optia Apheresis System Operator's Manual. It contains information and instructions on how to safely operate, transport, troubleshoot, and maintain the Spectra Optia system and the Seal Safe system. You should read and understand the information in this guide before operating the system. Use this guide in conjunction with the appropriate Spectra Optia Apheresis System procedure guide when performing a procedure on the system"

As described in the statement above, the system's *Essentials Guide* contains general information that is applicable to the general use of the system, while individual *Procedure Guides* provide protocol-specific instructions. This structure for the system's Operator's Manual has been previously cleared in BK120012, BK120076, and K131744.

Because the *Essentials Guide* is not specific to any particular protocol, the cleared indications statements are reserved for the *Procedure Guides* for each protocol. For this reason, Terumo BCT has only included the indications statements for the cleared Spectra Optia system procotols in their respective *Procedure Guides* and not be in the *Essentials Guide.* Terumo BCT recommends maintaining the same schema for the *Instructions for Use* (IFU) for the Exchange Set, to avoid confusion as it supports multiple protocols (TPE and RBCx).

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b. On page 4 of the RBCx Procedure Guide (Attachment 13.1), you state that "it is advisable to obtain the patient's detailed drug history before each apheresis procedure. For those drugs potentially affected by apheresis procedures, the physician either should adjust the doses or give the medications immediately after the procedure." Please also add that caution should be used when treating patients taking angiotensin-converting enzyme (ACE) inhibitors, given the potential effects, including facial flushing, as pointed out in your Clinical Investigation Report.

Given that each patient will present with a different set of health issues and therefore a different potential medication profile Terumo BCT cannot list all medications within the RBCx *Procedure Guide*. It is more appropriate to allow the treating physician to determine which medications may pose an issue before treating. The mention of ACE inhibitors was only an example of possible medications to consider for apheresis procedures. There is no mention of flushing within the Clinical Investigation Report. Terumo BCT is aware that FDA was concerned with flushing in 2009 related to apheresis procedures but as there were no reported events of flushing during the RBCx study it is not appropriate to list this effect.

As illustrated in the graphic below, Page 17 of the *Essentials Guide* contains a list of the potential known patient reactions to apheresis.

Preface

Adverse Effects of Apheresis Procedures

Be aware of possible patient reactions to apheresis procedures, and be prepared to take appropriate action should any reactions occur. Some previously reported reactions are:

- Anxiety
- Headache
- Light-headedness
- Digit and/or facial paresthesia
- Fever
- Chills
- Hematoma
- Hyperventilation
- Nausea and vomiting
- Syncope (fainting)
- Urticaria
- Hypotension
- Allergic reactions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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c. Please add a procedural warning for users to inspect disposable sets for kinks, since they may contribute to mechanical hemolysis.

A warning related to kinks is currently provided both on Page 7 of the *Procedure Guide* as part of General Tubing Set Caution #12 and on Page 2 of the Exchange Set IFU (provided below), and are in the same locations for other Spectra Optia protocols. Terumo BCT suggests that the warning remain at its current locations to maintain consistency across all Spectra Optia protocol protocols.

> The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:
>
> • Severe kinks in the tubing are apparent.
> • The tubing set appears to be incorrectly assembled.
> • The tubing set is damaged.
> • Any clamps are closed on the lines.

d. Additionally on page 4 of the RBCx Procedure Guide, you include a warning concerning cases where a blood warmer is used on the return line. Please also include recommendations on the maximum temperature setting that should be used during a procedure based on the clinical experience from your study.

Although an Astotherm Plus Blood Warmer (manufactured by Stihler Electronic GmbH) was provided to study sites, The Clinical Investigation Protocol (CIP) did not specify that a warmer must be used or any parameters for its use. The use of a blood warmer was at the discretion of the study investigator.

The Astotherm Plus Operator's Manual is provided in **Attachment D**, and states on Page 9 that the device has only three temperature settings - 37 °C, 39 °C, or 41 °C. Because of the blood warmer's limited temperature setting options, the fact that it is not required for the RBCx procedures, and because use of the blood warmer and temperature setting are at the discretion of the physician, Terumo BCT recommends that a specific recommendation should not be added to the *Procedure Guide*.

e. Page 6 of the RBCx Procedure Guide states that users should maintain "aseptic technique throughout all procedures to ensure patient safety and product quality." Since the RBCx Procedure Guide is for therapeutic RBCx procedures where no blood product is created, please revise this statement to remove references to a product.

Procedural Caution #4 (Page 6) in the *Procedure Guide* has been updated from **"**aseptic technique throughout all procedures to ensure patient safety and product quality." to "Use aseptic technique throughout all procedures to ensure patient safety." A copy of the updated *Procedure Guide* is provided in **Attachment E**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

f. Also on page 6 of the RBCx Procedure Guide, you note that the higher the inlet:anticoagulant (AC) ratio, the greater the risk for "aggregates and clumps" to form. Please define or describe the type of aggregates and clumps to which the labeling is referring.

Procedural Caution #6 (Page 6) in the *Procedure Guide* has been updated from "The higher the inlet:AC ratio used during the procedure, the greater the risk is for aggregates and clumps to form in the tubing set." to "The higher the inlet:AC ratio used during the procedure, the greater the risk is for platelet aggregates and clots to form in the tubing set." A copy of the updated *Procedure Guide* is provided in **Attachment E**.

g. Please move Procedural Caution # 31, page 6 of the RBCx Procedure Guide, regarding the hazardous nature of the disposable materials post-treatment, to the Warnings for Use section of the guide.

The *Procedure Guide* has been updated - Caution #31 is now Warning #20 on Page 5 of the guide. A copy of the updated *Procedure Guide* is provided in **Attachment E**.

h. On page 19 of the RBCx Procedure Guide, when describing the Depletion and Exchange phases, you explain that "the system returns Plasma and replacement fluid," or "Plasma and replacement RBC to the patient." Please clarify whether you are referring to allogeneic plasma (e.g., transfusion component), or the patients' autologous plasma. If the latter, please modify the device labeling to not capitalize the word "plasma," since that might imply a licensed blood component.

During the Depletion and Exchange phases, the plasma returned to the patient could be either allogenic or autologous. Therefore, we have changed both instances of "Plasma" to "plasma" on Page 19 the *Procedure Guide* as requested. A copy of the updated *Procedure Guide* is provided in **Attachment E**.

i. Some of the pre-clinical testing performed prior to your clinical study indicated that flow rates of 60 ml/min could not be achieved with 20-gauge needles without excessive return pressures. Please include this in your Procedure Guide. Please comment on whether any such problems were observed during the clinical study.

The intent of the Effect of Needle Gauge test documented in the pre-clinical study was to verify that the embedded system controls to notify the user if the needle gauge and flow rate combination are not compatible (e.g. pressure limit alarms) are functioning properly. Test results demonstrate that this system feature is functioning as intended. The example of the 20 gauge needle used at 60mL/min was included as a confirmation that the system appropriately detected this combination and prevented excessive return pressure.

As instructed on Page 20 of the *Procedure Guide*, determining the appropriate gauge needle to use for an RBCx procedure is up to the operator based on the desired flow rate for the procedure. In making this determination, operators consider the patient's size, the size of needle that the patient's vein will support, as well as the desired flow rate*. Because of the multiple factors that contribute to determining appropriate needle size and flow rate, it would not be possible to include every combination in the *Procedure Guide*. Therefore, Terumo BCT recommends maintaining the current instruction on Page 20 with respect to needle gauge.

Regarding the ESSENTIAL study, needle gauge was not captured on the eCRF nor were any needle-related issues reported. However, clinical study procedure data were reviewed for return pressure alarms. This analysis of the procedure information from each of the clinical study runs showed only two procedures that were not limited by AC infusion rate to flow rates of less than 60 ml/min. Procedure 04-105 was completed at an inlet flow rate of 65 ml/min, and procedure 05-102 was completed at an inlet flow rate of 60 ml/min. In neither case was a flow rate adjustment made due to excessive pressure alarms.

*In fact, some needles even state the supported flow rates on the packaging.

j. On page 22 of the RBCx Procedure Guide, you provide users with instructions to change a patient's total blood volume (TBV), if desired. Please explain why an operator might change this parameter and enter a different volume, rather than having the Spectra Optia® system calculate the TBV based on the patient's sex, height and weight parameters entered.

Standard practice not only in therapeutic apheresis, but other TBV-based activities such as medication dosing, requires the physician to determine appropriate TBV calculation method. Physicians conducting RBCx procedures on the Spectra Optia system may modify system settings at their discretion as appropriate for the patient. Pregnancy, extreme obesity, amputation, and muscularity are some factors that could require the physician to apply alternate calculations.

k. Please revise the RBCx Procedure Guide to provide a referenced table and or formula for calculating the TBV of pediatric boys and girls based on lean body mass.

As discussed in Question j above, standard practice not only in therapeutic apheresis, but other TBV-based activities such as medication dosing, requires the physician to determine appropriate TBV calculation method. This standard of practice also applies to pediatric patients.

The Spectra Optia RBCx *Procedure Guide* notifies the user on Page 22 that "If the patient weighs less than 25 kg (approximately 55 lb), the system does not display a TBV. You must calculate and enter the appropriate TBV for the patient." This instruction is based on a recommendation from the 3rd Edition of Apheresis: Principles and Practice[1] to manually confirm pediatric TBV calculated by automated apheresis devices using Nadler's formula (e.g. COBE Spectra), as Nadler's formula does not accurately calculate TBV for children. Since Spectra Optia does use Nadler's formula, but does not provide pediatric TBV, then one would conclude that manual calculation would be necessary for all pediatric patients.

Due to the standard of practice, issues with Nadler's formula and the variety of methods used to calculate TBV in children[2], Terumo BCT believes that the current labeling proposed for the RBCx protocol sufficiently instructs the operator to manually calculate TBV for pediatric patients.

l. When performing RBC exchange treatments, users will be asked to enter the average hematocrit of the replacement fluid being used. Please explain whether an actual hematocrit should be determined on each unit of RBCs being returned to the patient, since that may allow the Spectra Optia® to more accurately calculate the Target Hematocrit.

As demonstrated in the Clinical Investigation Report, the average hematocrit from <u>all</u> bags of replacement fluid used during a single procedure is adequate for Optia to achieve the desired final hematocrit for RBCx procedures.

Management of replacement fluid and how/when hematocrit is measured, is under control of the operator and their local policies and procedures. These institution-specific practices may be conducted in accordance with guidance from *Apheresis: Principles and Practices*[1], which states that "each institution should establish the <u>average</u> Hct of the RBC units it receives…"

m. Page 34 of the RBCx Procedure Guide instructs the operator to pause the system if the patient experiences citrate toxicity. Please comment on whether this step might cause clots to form in the extracorporeal circuit, and whether there is a maximum amount of time that a procedure may be paused before it must be discontinued. Please revise the labeling accordingly.

Clotting in the extracorporeal circuit is not an issue during a system pause due to the fact that anticoagulant is used during the procedure and remains in the circuit throughout the course of the procedure. Terumo BCT makes no recommendation to end a procedure for situations

[1] AABB, Apheresis: Principles and Practice, 3rd Edition. Maryland: AABB Press, 2010. Print.
[2] O. Linderkamp, H. T. Versmold, K. P. Riegel, K. Betke. Estimation and prediction of blood volume in infants and children. European Journal of Pediatrics. 1977, Volume 125, Issue 4, pp 227-234

other than system-related issues, which are detailed in the system labeling and software. The decision to end an RBCx procedure for any other reason is at the discretion of the physician and is likely defined by local transfusion practices. As the circuit remains anticoagulated after it exits the manifold where the AC mixes with the whole blood, we do not believe that any labeling revisions are necessary in this respect.

n. Please comment on whether a physician's presence is required during RBCx procedures and revise the labeling to include this recommendation, if applicable.

As per Caution #2 in the *Essentials Guide* (Page 9), "Each operator should be thoroughly familiar with the Spectra Optia system's operating instructions before using the system. All procedures should be performed by qualified medical personnel under the supervision of a physician." Physical presence of the physician during an RBCx procedure is subject to local policies and procedures.

Spectra Optia® Essentials Guide

o. As noted in Deficiency 4.b above, the review team recommends that a warning be added to the RBCx Procedure Guide concerning the treatment of patients on ACE inhibitors. Please add a similar warning to the Essentials Guide.

Please refer to the related response provided for Question 5.b.

p. On page 25 of the Essentials Guide, you describe the Automatic and Semi-Automatic Modes. Please explain whether the RBCx procedure calculations are correct if the system is operated in Semi-Automatic Mode, compared to Automatic Mode. Please revise the labeling if additional user instructions are necessary when using the Semi-Automatic Mode.

The Semi-Automatic mode is not available during RBCx procedures. Although this mode is described in the *Essentials Guide* (applicable to all Spectra Optia procedures), it is specifically not addressed in the RBCx *Procedure Guide* nor does it appear on the software graphical interface (GUI) for RBCx procedures. Therefore, no labeling revisions are necessary with respect to the RBCx protocol.

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q. You include a caution on page 70 of the Essentials Guide stating that "Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit. The attending physician is responsible for prescribing the anticoagulant used, however, and all personnel involved in performing apheresis procedures should read the anticoagulant manufacturer's product insert before use." Given this recommendation and the fact that only ACD-A was used in the clinical study, please modify the labeling so that it does not suggest that another anticoagulant may be used at the prescribing physician's discretion.

The *Essentials Guide* has been updated – this sentence was removed from the caution that appears on page 72, and well as the same cross-referenced caution #24 on page 12. A copy of the updated Essentials Guide is provided in **Attachment F**.

6. In the current submission, you explain that the same disposable set (Catalog # 10220) will be used to perform the TPE and RBCx procedures, and that the TPE treatments can be performed with either the single needle or double needle options. Please confirm whether the RBCx treatments will also be offered for single needle and double needle configurations.

The RBCx software is not currently configured to accommodate single-needle access. At such time that the software has been modified to support dual access for RBCx procedures, a new 510(k) notification will be submitted.

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Attachment A
Updated Clinical Investigation Report (CIR)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Investigation Report: CFR-5001

1 TITLE PAGE

Study Title:	Evaluation of the Spectra Optia® Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease
Protocol Number:	CTS-5001
Development Phase:	Pivotal
Study Design:	Prospective, open-label, single-arm, multi-center
Investigational Device:	Spectra Optia Apheresis System
First Patient Enrolled:	07 Nov 2012
Data Base Cut-off:	21 Jun 2013
Sponsor:	Terumo BCT, Inc. 10811 W. Collins Ave. Lakewood, CO 80215 (303) 231-4986
Sponsor Contact:	(b) (6) [redacted]
Coordinating Investigator:	
Principal Investigators:	Multicenter
Final Date:	25 Jul 2013

This study was conducted in accordance with Good Clinical Practices (GCP), including the archiving of essential documents.

Confidentiality Statement

The information contained herein is confidential and the proprietary property of Terumo BCT, Inc. Any unauthorized use or disclosure of such information without the prior written authorization of Terumo BCT, Inc. is expressly prohibited.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 SYNOPSIS

Sponsor Terumo BCT, Inc.
Name of Finished Product Spectra Optia Apheresis System – Red Blood Cell Exchange protocol
Study Title Evaluation of the Spectra Optia® Apheresis Red Blood Cell Exchange Protocol in Patients with Sickle Cell Disease
Protocol Number: CTS-5001
Investigator(s): Coordinating investigator = Keith Quirolo, MD
Study Center(s): multicenter study
Study Period 07 Nov 2012 to 21 Jun 2013
Purpose of the Study: To provide data to demonstrate that the Spectra Optia Apheresis System performs as designed for red blood cell exchange (RBCx) transfusion.
Objective The objective of the study was to evaluate the performance of the Spectra Optia System RBCx protocols (exchange and depletion/exchange) in study participants with sickle cell disease (SCD).
Methodology The study was a prospective, multi-center, single-arm, open-label study design. The planned enrollment was to included approximately 60 patients comprising the evaluable population (40 adults and 20 children). The intended patient population was to have SCD and to have an RBCx or RBC depletion/exchange procedure either as part of a chronic program or as a single procedure. The type of treatment procedure (RBCx or RBC depletion/exchange) was based on the investigator's recommendation. Interim analyses were conducted after 20 and 40 evaluable patients had completed the procedure to determine if the observed variability of the ratio of the fraction of actual cells remaining (FCRa) / predicted fraction of cells remaining (FCRp) is consistent with the planning estimates. An additional lead-in phase was conducted at each site to train operators on the use of the device for these procedures.
Number of Patients (Planned and Analyzed) It was anticipated that up to 72 patients may be needed to be enrolled in order to obtain 60 patients in the evaluable population and up to a maximum of another 20 patients enrolled as part of the lead-in phase. Therefore, the total projected enrollment was a maximum of 92 patients. A total of 73 patients were enrolled. One patient was found to be ineligible and

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was not treated or included in the full analysis set. The evaluable population was comprised of 60 patients. The full analysis set included the 60 patients from the evaluable population and 12 lead-in patients for a total of 72 patients.

Diagnosis and Main Criteria for Inclusion

Patients had to give informed consent (IC) or assent, be ≥ 12 years old and have SCD with a need for an RBCx procedure. Patients had to have sufficient venous access for the procedure and be able to commit to the follow-up schedule.

Test Product, Device

Spectra Optia Apheresis System

Duration of Treatment

Patients underwent either 1 RBCx or exchange/depletion procedure and had 1 follow-up assessment within 18-24 hours post-procedure.

Criteria for Evaluation

A patient was considered evaluable if he/she signed an IC/assent form, met eligibility criteria, were exposed to the study treatment, and for whom endpoint data were available without endpoint-affecting data entry errors that could not be resolved retrospectively. Lead-in patients were not included in the evaluable population but were included in the full analysis set. Safety analyses were conducted on the full analysis set.

Statistical Methods

Statistical outputs are descriptive. The primary efficacy endpoint was to determine the mean ratio defined by the FCRa to the FCRp in the evaluable population. Secondary endpoints included the following: procedural success of the Spectra Optia System in the evaluable population; the ability of the Spectra Optia System to achieve the desired final hematocrit (Hct) in the evaluable population; investigator satisfaction with the device and outcome of the procedure in the evaluable population; and device-related serious adverse events (SAEs) in the full analysis set.

Summary of Results

The efficacy analyses were conducted on data from all evaluable patients (n = 60). Twelve lead-in patients were enrolled but not included in the evaluable population; these patients are included in the full analysis set (n = 72).

The ratio of actual to predicted fraction of cells remaining following the RBCx procedure (0.92,) was well within the pre-specified boundaries. The tightness of the 95% CI (0.883, 0.963) indicates that the system functioned well. When these data were analyzed by type of procedure and age group, the results were consistent with the overall evaluable population.

All secondary endpoints were met as well. The procedural success rate was 100%. The Spectra Optia System was able to achieve the desired final Hct in the evaluable population (mean Hct = 1.03, median = 1.02). The investigator satisfaction rate was 100%.

The safety profile was favorable in this study. Thirteen patients (18.1%; 95% CI: 10.0%, 28.9%) experienced at least 1 adverse event (AE). The most frequently reported AEs regardless of causality were dizziness (n = 6, 8.3%), nausea (n = 4, 5.6%), and platelet count

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decreased (n = 4, 5.6%). All events were mild (Grade 1, n = 7, 9.7%) to moderate (Grade 2, n = 6, 8.3%) in severity. The only AEs considered related to the study device were 3 (4.2%) instances of platelet count decreased. Twelve of the 13 patients with AEs had events considered related to the study procedure. No patients had an SAE, unanticipated adverse drug effect (UADE), or withdrew from the procedure or treatment due to an AE.

Conclusions

The primary endpoint of the study was met. The ratio of actual to predicted fraction of cells remaining following the RBCx procedure (0.92,) was well within the pre-specified boundaries. The tightness of the 95% CI (0.883, 0.963) indicates that the system is functioning well. All secondary efficacy endpoints were met as well: 1) the procedural success rate was 100%; 2) the Spectra Optia System was able to achieve the desired final Hct in the evaluable population (mean Hct = 1.03, median = 1.02); and the investigator satisfaction rate was 100%.

The safety profile was favorable. Overall, 18.1% of patients experienced at least 1 AE regardless of causality; however, all events were mild to moderate in severity. The only AEs considered related to the study device were 3 instances of platelet count decrease and none required a platelet transfusion. No patients had an SAE, UADE, or withdrew from the procedure or treatment due to an AE.

Final Date: 25 Jul 2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment B
Lead-In Patient AE Data

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ESSENTIAL STUDY - LEAD-IN PATIENT AE DATA

SubjectID	Site	Adverse Event Term (AETERM)	Adverse Event Term Code (AETERM_CODED)	Adverse Event Term_Lowest Level Term (AETERM_LLT)	Adverse Event_Preferred Term (AETERM_PT)	Date of onset
03-503	3	Clot noted in patient proximal line and inlet tubing; Optia set unloaded and new set reloaded. Procedure restarted and completed without alarms	Hypercoagulation	Hypercoagulation	Hypercoagulation	11/8/2012
05-502	5	Worsening of bleeding at the location of the prot	Injection site bleeding	Injection site bleeding	Injection site haemorrhage	1/11/2013
05-502	5	More pain than usual at the site of the port after the RBCX procedure	Pain injection site	Pain injection site	Injection site pain	1/11/2013
04-501	4	lightheaded	Lightheadedness	Lightheadedness	Dizziness	2/28/2013
04-501	4	nausea	Nausea	Nausea	Nausea	2/28/2013
04-501	4	hypotension	Hypotension	Hypotension	Hypotension	2/28/2013
04-501	4	fainting	Fainting	Fainting	Syncope	2/28/2013
04-501	4	dizziness	Dizziness	Dizziness	Dizziness	2/28/2013
04-501	4	lightheadedness	Lightheadedness	Lightheadedness	Dizziness	3/1/2013

ESSENTIAL STUDY - LEAD-IN PATIENT AE DATA

SubjectID	Time of Onset	Timing	Date of resolution	Time of resolution	Malfunction of kit or device	Citrate reaction severiry scale	Severity	Relationship to Device	Relationship to procedure
03-503	10:55	During procedure	11/18/2012	11:42	NA	0: None	1: Mild	Unrelated	Possibly related
05-502	14:00	During follow-up	1/11/2013	14:00	NA	0: None	1: Mild	Unrelated	Possibly related
05-502	14:00	During follow-up	1/11/2013	14:00	NA	0: None	1: Mild	Unrelated	Possibly related
04-501	15:35	During follow-up	2/28/2013	16:35	NA	0: None	2: Moderate	Unrelated	Probably related
04-501	15:35	During follow-up	2/28/2013	16:35	NA	0: None	1: Mild	Unrelated	Probably related
04-501	15:35	During follow-up	2/28/2013	15:55	NA	0: None	1: Mild	Unrelated	Probably related
04-501	15:35	During follow-up	2/28/2013	15:36	NA	0: None	1: Mild	Unrelated	Probably related
04-501	15:35	During follow-up	2/28/2013	15:36	NA	0: None	1: Mild	Unrelated	Probably related
04-501		During follow-up	3/1/2013		NA	0: None	1: Mild	Unrelated	Unrelated

ESSENTIAL STUDY - LEAD-IN PATIENT AE DATA

SubjectID	Action taken for study device/procedure	Other, specify	Intervention/Treatment of event	Other, specify	Outcome	Serious Adverse Event (SAE)?
03-503	Other	proximal port deaccessed and reaccessed with new needle; Optia set unloaded and new set re-loaded	None		Recovered	No
05-502	None		None		Recovered	No
05-502	None		None		Recovered	No
04-501	None		Medication		Recovered	No
04-501	None		None		Recovered	No
04-501	None		Medication		Recovered	No
04-501	None		None		Recovered	No
04-501	None		None		Recovered	No
04-501	None		None		Recovered	No

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Attachment C
Updated 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 510(k) Summary

Terumo BCT requests that the attached Summary for this version of the Spectra Optia system be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this premarket 510(k) notification.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

Owner/Manufacturer:	Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	Tina O'Brien Senior Regulatory Affairs Specialist Phone: (303) 239-2082
Date of Summary Preparation:	August 2, 2013
Trade Name:	Spectra Optia® Apheresis System
Common Name:	Apheresis System
Classification Name:	Automated Blood Cell Separator
Product Code:	LKN
Predicate Device:	Spectra Optia Apheresis System

Device Description: The Spectra Optia Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major sub-systems: (1) the apheresis machine itself (centrifuge, pumps, valves, etc.), (2) sterile, single-use, disposable tubing sets and, (3) embedded software.

Modifications to the disposable Exchange Set and embedded software have been made to enable Red Blood Cell Exchange (RBCx) procedures on the Spectra Optia system.

Intended Use:
The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications, and may be used to perform Red Blood Cell Exchange, Depletion, and Depletion/Exchange (RBCX) procedures.

Indications for Use:
The Spectra Optia Apheresis System, a blood component separator, can be used to perform Red Blood Cell Exchange (RBCx) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Technological Comparison:
The system's base technology is not changed by the introduction of the RBCx protocol.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Discussion of Non-clinical Data:
The modified Spectra Optia system software was verified through a variety of verification testing; including Functional, Reliability, Usability, Exploratory, and Robustness.

Discussion of Clinical Data:
A prospective, multi-center, single-arm, open-label study was conducted to demonstrate that the Spectra Optia's RBCx protocol could consistently achieve the target HbS in the target population as prescribed by the physician. The study resulted in all primary endpoints being met with no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported.

Substantial Equivalence:
Provided below is a summary of substantial equivalence.

Table 1: Spectra Optia system vs. COBE Spectra

	Spectra Optia system (Subject Device)	***COBE Spectra system (K831004)***
Intended Use	Therapeutic Plasma Exchange and **Red Blood Cell Exchange**	Multiple therapeutic apheresis procedures, including **Red Blood Cell Exchange**
Essential Technology	Both the Spectra Optia and COBE Spectra systems are automated blood cell separators achieving their essential function (the separation of blood cells and plasma) through centrifugation.	
Software	Software algorithms underlying the red blood cell exchange procedures on both the Spectra Optia and COBE Spectra systems are controlled by the same equations.	
Performance	In both a "simulated-use" laboratory validation study and human clinical trial, Spectra Optia's RBCx protocol was found to perform the same as the COBE Spectra RBCx protocol, with respect to the system's ability to achieve patient hematocrit targets and to maintain patient fluid balance.	

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Attachment D
Astotherm Operator's Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating Instructions

ASTOTHERM®*plus*

Warmer for blood, infusion and irrigation solutions

Model AP220

Part-No. 0550.7200.12 NA, Rev.4 - 04/ 2008

STIHLER ELECTRONIC

STIHLER ELECTRONIC GmbH • 70597 Stuttgart • Germany

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

To be filled in by the user:

Serial number _____

Stock number _____

Device location _____

Date of commissioning _____

Manufacturer:
STIHLER ELECTRONIC GmbH
Julius-Hölder-Str. 36
70597 Stuttgart
Germany

Telephone:
Nat.: 0711/72067-0
Int.: +49-711-72067-0
E-Mail: info@stihlerelectronic.de

Telefax:
Nat.: 0711/72067-57
Int.: +49-711-72067-57

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 INTRODUCTION

INDICATIONS

The ASTOTHERM PLUS can be used to heat fluids supplied to the patient either to avoid or reduce hypothermia or to increase well-being.
Applications include transfusions, infusions, dialysis, haemofiltration and apheresis.

CONTRAINDICATIONS

No contraindications are currently known apart from those which may generally occur when infusions, transfusions or dialysis processes are used.

Follow the operating instructions! Any handling of the device assumes the accurate knowledge of and compliance with these instructions.

WARNINGS

- If the ASTOTHERM PLUS excessive temperature alarm is triggered, stop supply of fluid to the patient immediately.
- When the ASTOTHERM PLUS is combined with other electrical medical devices, the relevant standards must be observed (see EN 60601-1-1 *Safety requirements for medical systems*).
- When the ASTOTHERM PLUS is used as a component in a haemofiltration, haemodialysis or haemodiafiltration device, it must be ensured that the entire system meets EN 60601-2-16. The temperature of the fluid may not exceed 41 °C. The haemodialysis, haemofiltration or haemodiafiltration device must have an independent overtemperature cut-out (41 °C), which at the very least must be checked before every treatment.
- To ensure reliable disconnection from the power main, pull out the plug, if required.
- Do not use the ASTOTHERM PLUS in areas where an explosion could occur.
- In order to minimize the risk of electrical shock, do not remove the rear of the housing. Do not use power adapters or extensions, which interrupt the ground wire.
- In order to ensure the safety of user/patient, the application and servicing measures specified by the manufacturer must be carried out.
- The manufacturer will not be liable for user/patient safety if measures other than those specified by the manufacturer are applied in use, servicing and safety checks.
- Persons performing such measures must be appropriately qualified and trained.
- Only qualified persons authorized by the manufacturer may service and modify the device.
- Any electrical installations must comply with the national standards and regulations applicable in each case (e.g. DIN VDE 0107).

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- In the case of several devices being combined and connected (e.g. at multiple sockets), the sum of the leak currents must not exceed the permissible limit value.
- Only use sterile infusion sets marked as manufacturer approved for the ASTOTHERM PLUS.
- All disposable sterile infusion systems are intended for single use.
- Use only CE-marked accessories marked expressly as accessories for the ASTOTHERM PLUS (e.g. ASTOTUBE, see also Section 3).

SAFETY INFORMATION

- All applications involving the use of an ASTOTHERM PLUS warmer must performed under supervision of medically trained staff.
- When fluids are heated, it is possible for gas bubbles to form.
- Be aware of the potential for air emboli when using a blood and fluid warmer.
- Fully prime all filters, lines and disposable sets before starting an infusion.
- Make sure all connections of the complete fluid stream are fixed tightly to prevent inadvertent infusion of air into the fluidstream.
- Do not warm infusions containing soluted gas (e.g. bicarbonate).
- Extreme care should always be taken to ensure that a bolus of air does not pass to the patient.
- In order to minimize the risk of injury to patients or users, or the risk of damage to property, please notify your regional sales agent immediately of any of the following events. In such cases, do not use the ASTOTHERM PLUS until the appropriate corrective measures have been taken.
  - Damaged or worn power connecting cable or plug
  - Damaged housing, damaged front panel, front panel with poor adhesion
  - A device which has suffered a severe shaking, blow or fall
  - A device whose electronic components have been exposed to the effects of fluids
  - A device which has already given one person an electrical shock
  - A device which seems to overheat
- When attaching the warmer to an IV pole, follow the instructions of the IV pole manufacturer with regard to maximum load and the avoidance of tilting.
- ASTOTHERM PLUS is a medical electrical device. According to Medical Safety EMC standard EN 60601-1-2:2001, special precautions should be taken regarding electromagnetic compatibility of medial electrical equipment.
- Portable and RF communication equipment (especially mobile phones) may interfere with medical electrical equipment.
- High frequency surgical devices may interfere with medical electrical equipment
- CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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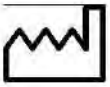
SYMBOLS

Insofar as these symbols are applicable, they appear in the relevant place on the device, in the packaging, on the rating plate, or in the accompanying paperwork.

Symbol: this shows that the device is a Type B defibrillation-protected part as per standards IEC 601-1 and VDE 0750 Part 1.

IP X4

Symbol: protected from water splashes



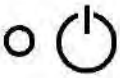
Symbol: appears before the manufacture year

Symbol: indicates the manufacturer.

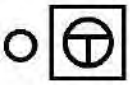
Symbol: indicates that, in order to use the device safely, accurate knowledge of the accompanying documents is required before using the device

Symbol: classified by UNDERWRITERS LABORATORIES INC. with respect to electric shock, fire and mechanical hazards only in accordance with UL2601-1 and CAN/CSA C22.2 No. 601-1.
The control number assigned for this file is 75JA.

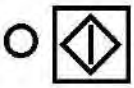
Control lamp: excessive or inadequate temperature alarm (look at temperature display)



Control lamp: stand-by mode



Key: "Device On/Off"
(press for at least 1 second to switch off)



Key: "Start", confirms temperature selected and starts the warmer heating process (keep depressed for approx. 1 second)

Key: "Increase" selected temperature

Key: "Decrease" selected temperature

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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COMPLIANCE WITH INTERNATIONAL STANDARDS

The ASTOTHERM PLUS was developed in compliance with the standards listed below:

EN 60601-1: 1990 + A1: 1993 + A2: 1995
Electrical medical equipment: Part 1: General requirements for safety

EN 60601-1-2: 2001
Electrical medical equipment: Part 1: Addition standard: Electromagnetic compatibility, requirements and tests

ASTM F 2172-02:
Standard Specification for Blood, Fluid Warmers

UL 2601-1
Medical Electrical Equipment, Part 1: General Requirements for Safety

CAN/CSA-C22.2 No. 601.1.1
Medical Electrical Equipment - Part 1: General Requirements for Safety - 1. Collateral Standard: Safety Requirements for Medical Electrical Systems

RESPONSIBILITY OF THE MANUFACTURER

The manufacturer is responsible for the safety, reliability and performance of the device only if

- All instructions described by the manufacturer for the use, servicing and operation of the device have been followed, and adequately trained and qualified persons perform these activities.
- Spare parts and components are replaced with original parts.
- Persons and service agencies expressly authorised to do so by the manufacturer perform assembly, modifications, or repairs.
- Electrical fittings conform to all the national standards applicable in each case.
- The ASTOTHERM PLUS is used in conformity with the operating instructions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WARRANTY TERMS

The warranty period for the ASTOTHERM PLUS is 12 months from the day of delivery to the purchaser.

Within the warranty period we will make good any defect attributable to poor materials or workmanship by repairing or replacing the device at our discretion.

Indirect damage is not subject to warranty. There is no claim under warranty for damage caused by mishandling or incorrect handling, use of force or normal wear and tear, or in the case of unauthorised intervention or modifications to the original state.

In the case of a claim under warranty or damage, return the defective device to STIHLER ELECTRONIC for repair. The cleaned device must be suitably packaged for transport so that no further damage is sustained and the repair becomes unnecessarily expensive. In any event, the customer must bear the expenses of transport and packaging.

SERVICE INFORMATION

The ASTOTHERM PLUS Warmer contains no user serviceable parts. Do not attempt to repair the ASTOTHERM PLUS Warmer yourself. Contact the local distributor for service or technical information. Only a qualified and trained engineer is allowed to carry out repairs to the ASTOTHERM PLUS.

Caridian BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215
USA
Phone: 303.232.6800
877.339.4228
Fax: 303.231.4160
www.caridianbct.com

Caridian BCT Europe NV/SA
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: 32.2.715-05-90
Fax: 32.2.721-07-70
www.caridianbct.com

The manufacturer can provide a service manual on request to make it possible for appropriately trained and qualified staff to repair those parts of the device that the manufacturer deems it possible to repair.

However, providing of technical documents or spare parts does not constitute authorization by the manufacturer to open or repair the device.

RETURNING A USED PRODUCT

If the device has been in contact with blood or bodily fluids, it needs to be carefully cleaned and disinfected.

In view of the risk of contamination with viruses and other pathogens, adequate precautions should always be taken to prevent contact with such pathogens. We recommend placing the device in a plastic bag and sealing this tightly before returning it.

The device should be packed in the original packaging (or equivalent) to avoid transport damage. The customer is responsible for correctly packaging and marking the product for return.

DISPOSING OF DEVICES

Please follow the regional regulations on the disposal of old devices or send the old cleaned and disinfected device to STIHLER ELECTRONIC or to your local distributor with an explanatory note. Following these regulations ensures your old device will be disposed of appropriately.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 PRODUCT DESCRIPTION

INTRODUCTION

The ASTOTHERM PLUS can be used to heat fluids supplied to the patient either to avoid or reduce hypothermia, or to increase comfort.
Applications include transfusions, infusions, dialysis, haemofiltration, and apheresis.

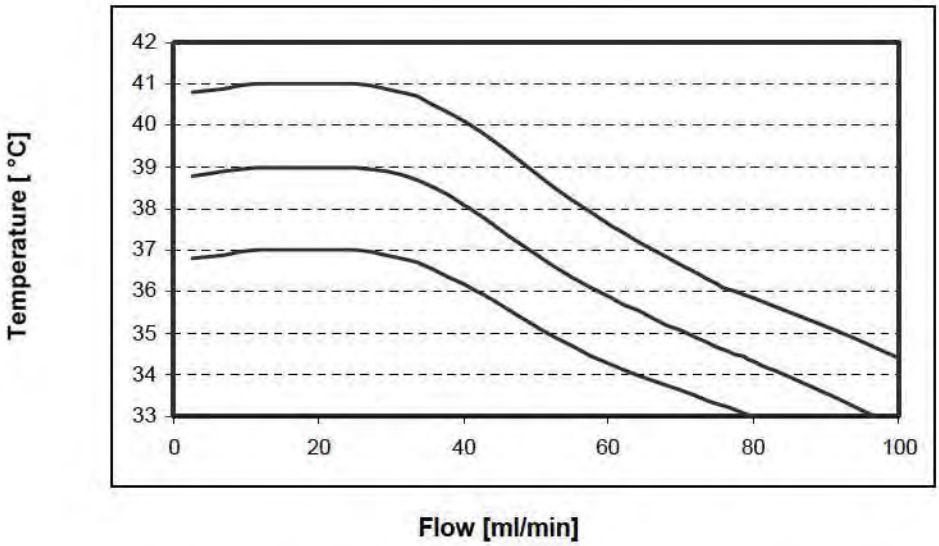
TECHNICAL DESCRIPTION

The warmer works in accordance with the principle of flow heating. In other words, the heat is transferred from the heat exchanger via the sterile ASTOTUBE disposable tubing to the fluid flowing through it.

The temperature of the ASTOTHERM PLUS can be selected to be 37 °C, 39 °C, or 41 °C. The temperature display always shows the current mean temperature of the **heat exchanger**. Heating of the fluid is based on flow rate and temperature of the fluid at the inlet (see diagram of outlet temperature).

Temperatures on the ASTOTHERM PLUS 220

Settings 37/39/41 °C, device outlet temperature, initial temperature 20 °C



10 ml/min = 0.6 l/h	40 ml/min = 2.4 l/h	70 ml/min = 4.2 l/h
20 ml/min = 1.2 l/h	50 ml/min = 3.0 l/h	80 ml/min = 4.8 l/h
30 ml/min = 1.8 l/h	60 ml/min = 3.6 l/h	90 ml/min = 5.4 l/h

If the entire heating output is not required, it is possible to insert a single IV tubing in the first half of the heat exchanger and another IV tubing in the second half of the heat exchanger. A check on heat exchanger temperature at both the inlet and outlet prevents fluids from overheating, even if they have different inlet temperatures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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COMPONENTS OF THE WARMER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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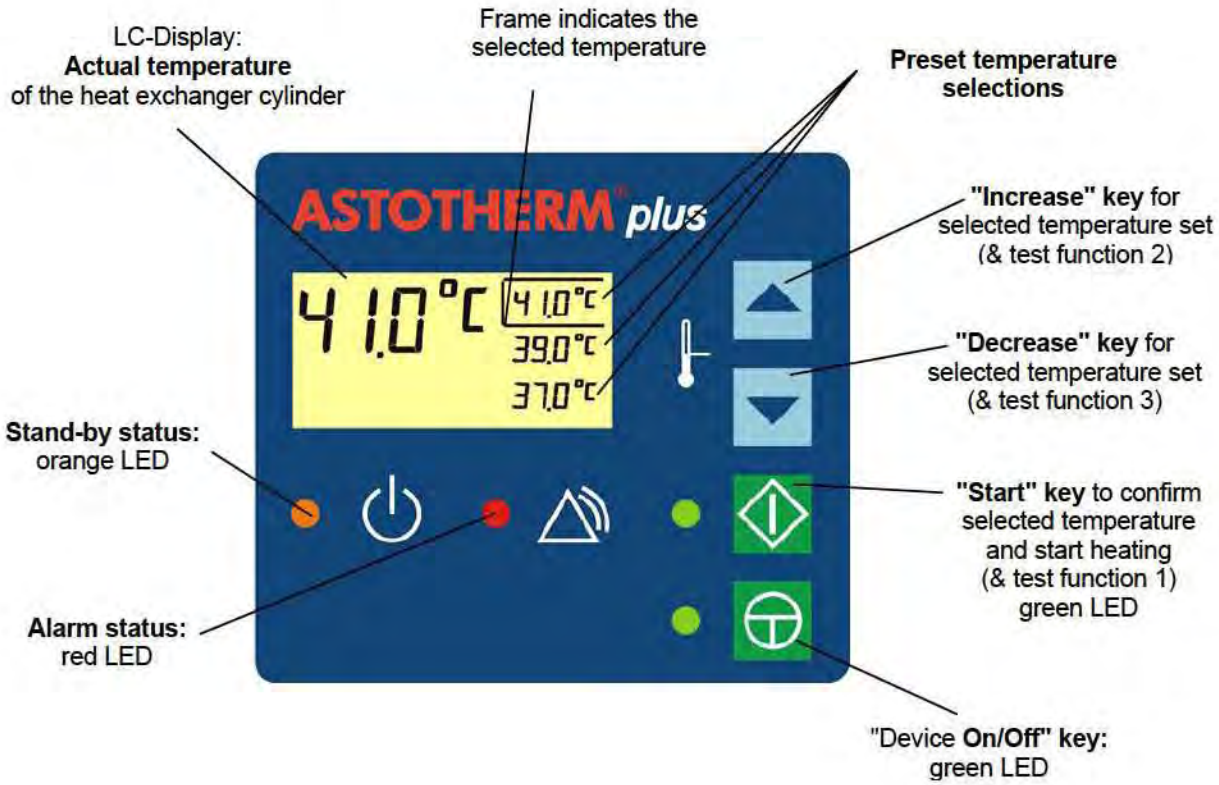
CONTROL PANEL COMPONENTS



WARMER CONDITIONS

Condition	Device display	Device activity
Stand-by	• Orange Stand-by LED on	• No activity
Device **On**	• Green Device LED on • Temperature Display on • Alarm LED flashing red • Alarm sound on • Start LED flashing green	• Device "waiting" • Confirm with "Start" key
Start heating	• Green Device LED on • Temperature Display on • Alarm LED off or flashing when device cold • Alarm sound off • Green Start LED on	• Heating on • Temperature control on • Temperature monitoring on

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 INSTALLATION

The ASTOTHERM PLUS is not approved for use in areas where an explosion could occur!

- The ASTOTHERM PLUS can be attached to an IV pole (12 mm to 35 mm diameter) or other device rail using the integrated clamp. The user should ensure that the ASTOTHERM PLUS unit is properly secured to the IV pole or other device rail in such a way as to prevent the device from disengaging or tipping.

- The ASTOTHERM PLUS is designed for the voltage range specified on the rating plate.

- According to our current knowledge, when the ASTOTHERM PLUS is combined with other medical equipment, the following effects may occur as a result:
  - Loss of pressure of up to 50 mm Hg caused by the ASTOTUBE disposable tubing required and dependent on the flow rate
  - Bubble formation due to evolution of gas in the heated fluid
  - Increase in total leakage current

- When combined with other electrical equipment, ensure that the ground wire potential is identical.

ASTOTUBE disposable tubing are CE-marked original accessories for the ASTOTHERM PLUS.

ASTOTUBE disposable tubing required (CE, sterile, use once only)	
Design:	**ASTOTHERM® *plus* 220**
Number of windings	maximum 11
External diameter	4 mm
Order no. PVC Filling volume Length	IFT40410 42 ml 592 cm (233 inches)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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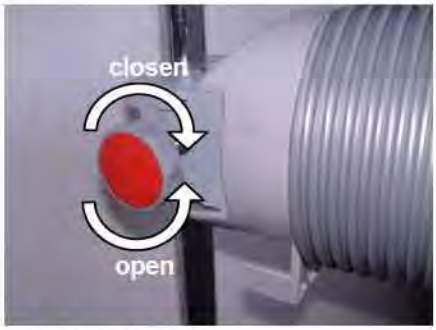
4 OPERATION

Clamp the ASTOTHERM PLUS to the IV pole following the steps below:



1. Loosen the clamp by turning the clamp knob counter clockwise.
2. Place the clamp around the IV pole on which you want to install the warmer.
3. Tighten the clamp by turning the clamp knob clockwise until the warmer is securely attached to the IV pole.

Ensure that the housing and front panel of the ASTOTHERM PLUS is not damaged in any way.

STARTING THE ASTOTHERM PLUS WARMER

1. Plug in the ASTOTHERM PLUS unit. The orange LED illuminates indicating stand-by status ○ ⏻ .
2. Turn on the device by pressing the Device On/Off key ⏻. The orange LED turns off, and the green LED next to the Device On/Off key illuminates and remains steady. The alarm status LED flashes red, the Start key ◇ flashes green, the temperature display turns on and the alarm sounds. Ensure that the alarm (red LED and alarm sound) is activated.
3. Select temperature using the △ or ▽ keys.
4. To start heating, press the "Start" key ◇ for approximately one second. The acoustical alarm turns off, and the green LED next to the Start key becomes steady. The alarm status LED continues to flash red indicating low temperature until the actual temperature of the device is approximately 4 °C below the selected temperature. Note: the unit may click briefly when the start key is pressed. This is normal. The alarm testing devices are reset and the heating starts until 35 °C is reached after approximately one minute. The device then regulates itself to the temperature set.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTALLING THE ASTOTUBE DISPOSABLE TUBING ON THE HEAT EXCHANGER

Install the ASTOTUBE disposable tubing onto the heat exchanger of the ASTOTHERM PLUS following the steps below:

a. Slide the female luer lock end of the ASTOTUBE disposable tubing under the rear bracket of the ASTOTHERM PLUS.

b. Insert the ASTOTUBE disposable tubing into the grooves of the heat exchanger while winding the ASTOTUBE disposable tubing around the heat exchanger in a counter clockwise direction. Gently pulling on the ASTOTUBE disposable tubing makes it easier to insert and improves seating of the ASTOTUBE disposable tubing.

c. Slide the male luer end of the ASTOTUBE disposable tubing into the front bracket.

d. Attach the male and female luer ends of the ASTOTUBE disposable tubing to the line(s) of the equipment with which it is being used according to the equipment manufacturer's guidelines.

ENDING THE ASTOTHERM PLUS WARMER OPERATION

1. Press the On/Off key ⏻ for approximately 1 second (all indicators go out, standby LED comes on).
2. Disconnect the ASTOTUBE disposable tubing from the equipment with which it is being used.
3. Remove the ASTOTUBE disposable tubing from the heat exchanger.
4. Disconnect the device from the power main and pull out the plug, if necessary.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 ALARM SYSTEMS AND TROUBLESHOOTING

EXCESSIVE TEMPERATURE ALARMS

Overheating is prevented by the following measures:

- Two separate temperature control sensors, a temperature display, and an excessive temperature safety cut-off
- Additional independent temperature sensor for excessive temperature safety cut-off
- Visual and acoustic alarm display

LOW TEMPERATURE ALARM

If the displayed temperature of the heat exchanger drops more than 4 °C below the selected temperature, the low temperature alarm will be activated.

ALARM REACTIONS

Type of alarm	Device display	Possible reasons	Recommended measures
Excessive temperature alarm Heating goes off	• Green Start LED flashes. • Red Alarm LED flashes. • Alarm sounds. **Look at temperature display!**	1. Inlet temperature of the fluid to be heated is too high. 2. Influence of an external heat source (e.g. radiator, sunlight, increasing ambient temperature). 3. Blood warmer is defective.	Note: After steps 1 or 2 below have been carried out and the blood warmer has cooled down, press the "Start" key. 1. Allow fluid to cool down. 2. Stop influence of external heat source or change location. 3. Warmer needs repair. Return device to manufacturer.
Low temperature alarm Heating stays on	• Green Start LED illuminates. • Red Alarm LED flashes. • Alarm sounds for 15 seconds after 2 minutes. **Look at temperature display!**	1. Inlet temperature of the fluid to be heated is too low, or flow rate is too high. 2. Blood warmer is defective.	Note: Alarm stops automatically if the reason for the alarm is eliminated. 1. Decrease flow rate somewhat. 2. Warmer needs repair. Return device to manufacturer.
Software fault	• Red Alarm LED flashes. • Alarm sounds. • Green LEDs are off.	1.Temporary program fault 2. Permanent program fault	1. Unplug device, wait 1 minute, switch on again, or simultaneously hold the keys "increase temp." and "decrease temp" for about 3 seconds. 2. Return device to manufacturer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 CLEANING AND DISINFECTION

Always unplug the ASTOTHERM PLUS before cleaning and disinfecting!

Clean your ASTOTHERM PLUS regularly. Regular cleaning and care by the user increases service life and ensures that the specified performance characteristics are always achieved.

CLEANING

To clean the surface of the housing, use a soft cloth and a mild soap solution or a special cleaning agent for plastic. Commercially available cotton swabs are suitable for cleaning the heat exchanger groove.

Never immerse device completely in fluid or bring into contact with steam!

DISINFECTION

For disinfection, use alcohol-based disinfectants of the "ready-to-use spray disinfectant" type containing low quantities (<0.2%) of aldehydes, or 0.25%-strength bleach solution (sodium hypochlorite).

The operator should not use any cleaning or decontamination methods other than those recommended. If using other methods, check with the manufacturer that these will not damage the device.

Under no circumstances sterilise with steam, hot air or thermochemicals

SERVICING

The ASTOTHERM PLUS is maintenance-free. There are no parts subject to wear.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7 QUALITY CONTROL

(UPON INSTALLATION AND EVERY 24 MONTHS)

- Check heat-up time.
- Check temperature control.
- Check excessive temperature alarms (tests 1 and 2).
- Test low temperature alarm (test 3).

Follow all additional regulations governing the use of medical devices!
Note: To check the protective grounding, the test point must penetrate the anodised coating of the heat exchanger cylinder.

CHECKING HEAT-UP TIME

Turn on the ASTOTHERM PLUS and press the "Start" key to start heating. After one minute, the temperature on the display should exceed 35 °C.

CHECKING TEMPERATURE CONTROL

For this test a calibrated thermometer* with a sensor tip with a maximum diameter of 3.5 mm is required. Turn on the ASTOTHERM PLUS and start heating by pressing the "Start" key. After about five minutes the temperature of the heat exchanger cylinder is completely even, allowing the measurement to be performed. Avoid direct sunlight and drafts during this test.

1. Insert the thermometer into the rear measuring bore on the side of the heat exchanger.
2. Monitor the thermometer and wait until the maximum temperature is indicated. The difference between the thermometer and the temperature display **should be no more than + 0.5 °C and – 1.0 °C**.

**Note*: Fever thermometers are designed as immersion sensors. To reach an exact measuring result the thermometer should immerse deep enough (depends on manufacturer and type). Because of using only the metal tip of the thermometer an incorrect measuring could be possible.

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CHECKING EXCESSIVE TEMPERATURE ALARMS

The ASTOTHERM PLUS has alarm test functions that simulate the failure of the temperature sensors and activate the safety cut-off feature.

Test 1: Start the device at middle temperature setting. Press the "Start" key for 3 seconds to start the internal test cycle. The LCD alternately shows **"t1"** and the actual temperature. After a short time, the excessive temperature alarm should occur (cf. Section 5).

Warning: If an alarm does not occur, the device must be repaired before use!

Re-start the device by pressing the "Start " key .

Test 2: Start the device at the highest temperature setting. Press the "Increase" key for 3 seconds to start the internal test cycle. The LCD alternately shows **"t2"** and the actual temperature. After a short time, the device should react with the excessive temperature alarm (cf. Section 5).

Warning: If an alarm does not occur, the device must be repaired before use!

Re-start the device by pressing the "Start " key .

CHECKING LOW TEMPERATURE ALARM

Test 3: Start the device at lowest temperature setting. Press the "Decrease" key for 3 seconds to start the internal test cycle (the heating stays off). The LCD alternately shows **"t3"** and the actual temperature. Once the device has cooled to 4 °C (± 1 °C) below the lowest selected temperature, the low temperature alarm should occur (cf. Section 5).

Warning: If an alarm does not occur, the device must be repaired before use!

Turn off the device using the "Device On/Off" key .
After this test, the device cannot be re-started by pressing the "Start" key .

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8 GENERAL TECHNICAL DATA

ASTOTHERM PLUS	**AP220 NA**		
Power supply cord	Hospital Grade Plug NEMA 5-15P SJO, SJT 18/3		
Electrical connection	100-115 VAC ±10% 47-63 Hz		
Impedance of protective grounding	≤ 0.2 Ω		
Insulation resistance	> 2 MΩ		
Leakage current	≤ 0.2 mA		
Primary fuses	2 x T4H (5x20)		
Secondary fuses	2 x 0.63 A		
Power consumption	max. 450 W		
Self-start after main power failure	5 to 30 sec.		
Protection class IEC 601-1	I		
Protection level to IEC 601-1	Type B defibrillation-proof applied part		
Humidity protection	IP X4		
FDA regulatory class	II		
UMDNS Code	10-447		
Dimensions height x width x depth	145 mm x 135 mm x 295 mm		
Weight	2.9 kg		
Heating-up time	Approx. 1 min (20 °C to 35 °C)		
Operating mode	Continuous operation		
Permissible environmental conditions: Operation: Storage:	Humidity: 10% to 90% 10% to 90%	Temperature: 0 °C to 32 °C -20 °C to 60 °C	Pressure: 700 hPa to 1060 hPa 500 hPa to 1060 hPa
3 selectable control temperatures	37 °C / 39 °C / 41 °C (± 0.5 °C)		
1st Safety temperature cut-off 2nd Safety temperature cut-off	42.5 °C (± 0.5 °C) 43.5 °C (± 0.5 °C)		
Heating element bimetal switch	65.0 °C (± 5 °C)		
Low temperature alarm	4 °C (± 1 °C) below control temperature		

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Attachment E
Updated RBCx Procedure Guide

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Spectra Optia®

Apheresis System

TERUMOBCT
Unlocking the Potential of Blood

RBCX

Red Blood Cell Exchange (RBCX) Procedure Guide

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Spectra Optia® Apheresis System

Red Blood Cell Exchange (RBCX) Procedure Guide

TERUMOBCT

Part No. 777377-804
Reorder No. 703957-000
2013-10

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Spectra Optia® Apheresis System device and tubing sets may be covered by one or more of the following patents:
United States: 5674173, 5676644, 5676645, 5722926, 5734464, 5795317, 5824881, 5906570, 5913768, 5919154, 5921950, 5936714, 5939319, 5941842, 5951877, 6053856, 6071422, 6200287, 6234989, 6280406, 6334842, 6361518, 6409696, 6497674, 6514189, 6730055, 6764460, 6773413, 6790195, 6899691, 6945948, 7029430, 7108672, 7169352, 7327443, 7354415, 7355685, 7422693, 7513882, 7549956, 7556611, 7605388, 7608053, 7671975, 7704454, 7780618, 7824355, 7828709, 7906771, 7943916, 7951059, 8057376, 8062202, 8066888, 8070663, 8088090, 8241196, 8337379, 8449439
and counterpart foreign patents:
Canada: 2527667
France: 2207023
Germany: 60035474.1, 60036906.4, 60041426.4, 60044623.9, 60044624.7, 60145279.8, 69618453.2, 69634860.8, 69636518.9, 69637310.6, 69637706.3, 69638219.9, 69638403.5, 69733198.9, 69739552.9, 69820404.2, 69836648.4, 69840459.9, 69842455.7, 602004027910.2, 602008010061.8. 602004041451.4
Great Britain: 2220477
Japan: 4099240, 4194667, 4304264, 4331204, 4382322, 4425938, 4459263, 4536806, 4746055, 4771595, 4886004, 5209737
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Preface

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About This Guide

This guide contains instructions for performing Red Blood Cell Exchange (RBCX) procedures on the Spectra Optia Apheresis System. Use this guide in conjunction with the *Spectra Optia Apheresis System Essentials Guide* when performing procedures on the system.

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Spectra Optia Apheresis System

Intended Use

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications, and may be used to perform Red Blood Cell Exchange, Depletion, and Depletion/Exchange (RBCX) procedures.

Indications for Use

The Spectra Optia Apheresis System, a blood component separator, can be used can be used to perform Red Blood Cell Exchange (RBCX) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Contraindications for Use

There are no known contraindications for use of the Spectra Optia system except those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

Warnings and Cautions for Use

Below is a list of warnings and cautions that apply to the use of the Spectra Optia system when performing RBCX procedures. See the *Spectra Optia® Apheresis System Essentials Guide* for a complete list of warnings and cautions that apply to the use of the system and the Seal Safe system. Although this information may also appear in other sections of the guides, the operator should read and understand the information listed in both publications before using the system.

Warnings for use

Procedural warnings

1 Follow standard transfusion practices for cellular components during RBCX procedures.

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2 Platelets are removed with Red Blood Cells during an RBCX procedure. The approximate percent of Platelets removed depends on the number of total blood volumes (TBV) processed, as shown in the table below. It is the physician's responsibility to determine the appropriate treatment for the patient.

TBV Processed	Platelets Removed (Approximate%)
0.5	39
1.0	63
1.5	78
2.0	86

3 It is advisable to obtain the patient's detailed drug history before each apheresis procedure. For those drugs potentially affected by apheresis procedures, the physician should either adjust the doses or give the medications immediately after the procedure.

4 The operator must verify the correct input of information relevant to the safety of each apheresis procedure.

5 When preparing to perform a procedure, ensure that the lines are connected to the correct fluids, and that fluid is flowing into the drip chambers:

- AC line (orange) to the anticoagulant container
- Saline line (green) to the normal saline (0.9%) container

6 Check that the tubing is correctly loaded in all pumps before starting a procedure. Visually inspect each pump to ensure that tubing does not protrude.

7 Before starting a procedure, inspect all lines, especially those in the centrifuge and on the front panel to ensure they are not obstructed. Tubing that is occluded or mechanically constrained can lead to malfunction or fluid imbalance. Inlet and return lines perform without difficulty as long as the interior diameter of the tubing is larger than the interior diameter of the patient's inlet and return access.

8 Only blood or blood products should be processed in the centrifuge.

9 Do not connect the patient before the system instructs you to do so.

10 Rigorous attention should be paid to proper venipuncture site selection and decontamination.

11 If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

12 Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

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13 Before connecting the patient, ensure that the AC line contains anticoagulant at the inlet manifold.

14 The inlet and return pressure sensors are not intended to detect infiltrations of the vein. Monitor the patient for infiltrations.

15 Tubing sets may occasionally fail, which could result in the loss of blood, blood products, or the introduction of air into the tubing set. It is very important that the operator watch for leaks in the cassette, all tubing and welds, and in the channel while the set is in use. Operators should take adequate precautions in handling blood and blood products in accordance with their facility's standard operating procedures.

16 When handling extracorporeal blood circuits, take adequate precautions to prevent the possible exposure to and transmission of infectious diseases.

17 The following can cause fluid imbalance:

- Administration of replacement fluid that is not at room temperature during a procedure
- Use of improperly vented fluid containers
- Equipment malfunction
- Improperly clamped or closed lines, or improperly loaded valves
- Use of inadequately primed or clotted filters on the replace line of the Exchange Set
- Tubing that is incorrectly loaded in the pumps

18 Terumo BCT does not recommend performing rinseback during RBCX procedures. The data the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

19 Do not touch **Unload** to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

20 All used disposable materials should be considered hazardous, and should be handled and disposed of at the end of the procedure in accordance with all applicable regulations.

Solution and medicinal fluid warnings

21 When using biologically-derived replacement fluids, closely monitor the patient for reactions.

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Cautions for use

Procedural cautions

1. The Spectra Optia system has many safety features. However, a patient reaction can occur rapidly. Therefore, it is imperative that the operator monitor the patient and the system throughout the procedure.
2. The physiological condition of patients may affect the outcomes of procedures performed on the Spectra Optia system.
3. Patients with impaired or abnormal citrate metabolism (for example, if the patient has liver or renal disease) may present an increased risk of citrate sensitivity. Attending physicians should assess the appropriateness of such patients for apheresis procedures and prescribe how they should be monitored during procedures.
4. Use aseptic technique throughout all procedures to ensure patient safety.
5. Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit.
6. The higher the inlet:AC ratio used during the procedure, the greater the risk is for platelet aggregates and clots to form in the tubing set.
7. For patient comfort and optimal system operation, be sure that the fluids used during the procedure are at room temperature before connecting them to the tubing set.
8. Do not connect the fluids to the tubing set before the system instructs you to do so.
9. To avoid a failed test of the tubing set, do not raise and lower the cassette after there is fluid in the set.
10. If you leave the roller clamp on the saline line completely open when the patient is connected, you will quickly infuse a large amount of saline to the patient.

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General tubing set cautions

11 The tubing set is intended for single-use only to ensure sterile tubing conditions. Do not resterilize the set.

12 The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:

- Severe kinks in the tubing are apparent.
- The tubing set appears to be incorrectly assembled.
- The tubing set is damaged.
- Any clamps are closed on the lines.

13 You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.

14 Do not stretch the tubing when folding the channel to install it in the centrifuge to avoid damaging the tubing set.

15 Use only your fingers to load the channel into the filler. To avoid puncturing the channel, never use a sharp object.

16 Do not seal the inlet line of the four-lumen tubing. Sealing the line could cause the tubing set to fail when you raise the cassette to unload the set.

17 Ensure all luer connections are secure.

Exchange Set cautions

18 Do not use the Exchange Set if the end caps are not in place.

19 Leave the cap on the unused luer (on the remove bag) to prevent fluid leakage. Ensure the cap fits tightly.

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Replacement Fluids Administered During RBCX Procedures

The physician is responsible for prescribing the replacement fluids for the RBCX procedure. The prescription should consider patient fluid status and other pertinent factors the physician believes may impact the patient's condition.

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Configuration and Procedure Data Management

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Configuring the Spectra Optia System

The Spectra Optia system allows you to configure procedure-independent and procedure-specific operating parameters to meet your facility's requirements. Configuration settings for the procedure-independent parameters apply to all procedures. Configuration settings for procedure-specific parameters apply to only the specified procedure type. Several parameters have a default setting. The system uses the default setting unless you enter a different setting. You must touch **Confirm** after you finish configuring the parameters in order for the settings to take effect.

To configure the parameters, perform the following steps:

1. Touch the **Config** menu button. The configuration tabs appear.
2. Touch the tab for the parameters that you want to configure. The corresponding configuration screen appears.
3. Touch the button for the parameter that you want to configure:
   - For parameters with only two settings, toggle between the settings until the setting that you prefer appears on the button.
   - For parameters with more than two settings, a list appears to enable you to select a setting.
   - For parameters that require a numeric setting, a data entry pad appears to enable you to enter a number. The range of acceptable values appears on the data entry pad.
4. Repeat step 3 until you finish configuring the parameters.
5. Touch **Confirm**.

Configuring Procedure-Independent Operating Parameters

See the *Spectra Optia® Apheresis System Essentials Guide* for instructions on configuring procedure-independent operating parameters.

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Configuring Procedure-Specific Operating Parameters

You may configure procedure-specific operating parameters after you select the procedure and before you connect the patient. The only configuration settings that you can change during the run are the inlet pressure and return pressure alarm limits.

RBCX operating parameters

Touch the **RBCX** tab to access the RBCX procedure configuration screen. Table 2-1 shows the parameters and setting options to configure on this screen.

Table 2-1: RBCX procedure configuration parameters and setting options

Parameter	Description	Setting Options
Maximum AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The rate configured represents the maximum rate at the start of the procedure.	0.8 to 1.2 (Default is 0.8)
Inlet:AC ratio (__:1)	Ratio of the inlet flow rate to the AC flow rate. The ratio configured represents the ratio at the start of the procedure.	6.0 to 15.0 (Default is 13.0)
Pressure alarm limit: Inlet (mmHg)	Limit at which an inlet pressure alarm occurs	-100 to -250 (Default is -250)
Pressure alarm limit: Return (mmHg)	Limit at which a return pressure alarm occurs	200 to 400 (Default is 400)
Custom prime recommendation (% TBV)	Percent of TBV or RBC in mL in the tubing set at which the system prompts you to consider performing a custom prime	• 10 • 15 (Default is 15)
Custom replacement fluid (%)	Percent of citrate in the custom replacement fluid	0 to 25 (Default is 0)
Fluid balance limit (% TBV)	Percent of total blood volume (TBV) in mL used to calculate the upper and lower caution limit for fluid balance. For example, if the patient has a TBV of 4 L and the limit is set at 10%, the system will notify you if the fluid balance exceeds +/- 400 mL.	5 to 15 (Default is 5)

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Blood warmer operating parameters

Touch the **Blood Warmer** tab to access the blood warmer configuration screen. Table 2-2 shows the parameters and setting options to configure on this screen.

Table 2-2: Blood warmer configuration parameters and setting options

Parameter	Description	Settings Options
Return line	Indicates if a blood warmer is connected to the return line. The system will instruct you when to connect the blood warmer tubing set before you connect the patient.	• Yes • No (Default is No)
Tubing volume (mL)	Volume of the blood warmer tubing set on the return line. The system uses this information to adjust the calculation for the extracorporeal volume, minimum volume required for a custom prime, and volume of saline required for rinseback.	1 to 100 (Default is 40)
Replace line	Indicates if a blood warmer is connected to the replace line during a procedure using an Exchange Set.	• Yes • No (Default is No)

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Entering Data During the Procedure

The Spectra Optia system requires that you enter specific data, such as fluid data, during an RBCX procedure. You may also change numerical values for certain operating parameters as you monitor the run. Table 2-3 shows data entry ranges for the parameters according to the screen on which the data entry buttons appear. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad also displays the established range for the parameter, or the calculated range if the range adjusts based on related data.

Table 2-3: Data entry ranges for RBCX procedure parameters

Screen	Parameter	Range
Patient data	Height: • ft • in • cm	• 1 to 8 • 12 to 96 • 30 to 244 (Value entered cannot be changed after run starts.)
	Weight: • lb • kg	• 5 to 500 • 2 to 227 (Value entered cannot be changed after run starts.)
	Hct (%)	10 to 80 (Value entered cannot be changed after run starts.)
	TBV (mL)	300 to 15000 (Value entered cannot be changed after run starts.)
Fluid data	Replacement fluid Hct (%)	10 to 80
	Fluid balance (mL or %)	-25% of TBV + suggested rinseback volume to +25% of TBV (Caution status applies if entry exceeds configured limit)

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Table 2-3: Data entry ranges for RBCX procedure parameters (continued)

Screen	Parameter	Range
Custom prime data entry	RBC unit Hct (%)	25 to 80
	Maximum inlet flow rate (mL/min)	5.0 to 120.0
	Volume (mL)	100 to 400
Main run	Maximum inlet flow rate (mL/min)	5.0 to 142.0
	Replace volume (mL)	10 to 10000
	Maximum AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2.0 to 50.0 (Warning appears if entry exceeds 15.0.)
Exchange status	Current patient Hct (%)	10 to 80
Bolus	Volume (mL)	From 10 to an amount based on hypervolemia limit of 25% of TBV
	Flow rate (mL/min)	10.0 to 120.0
Run values	Maximum AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2.0 to 50.0 (Warning appears if entry exceeds 15.0.)
	FCR (%) • Starting defective RBC (%) • Target defective RBC (%)	1 to 99 • 10 to 100 • 1 to 99 (Adjusts based on starting defective RBC entered.)
	Minimum Hct (%)	20 to current patient Hct minus 2 (Could be lower if patient has a small TBV.)
	Target Hct (%)	20 to 60

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Table 2-3: Data entry ranges for RBCX procedure parameters (continued)

Screen	Parameter	Range
	Replaced (mL): Exchange	10 to 10000
	Maximum inlet flow rate (mL/min)	5.0 to 142.0
Options	Blood warmer: Tubing set volume (mL)	 1 to 100 (Default volume is 40.)
Rinseback	Return flow (mL/min)	2.0 to 100.0
Run targets	Target Hct (%)	20 to 60
	FCR (%)	1 to 99
	Replaced (mL): Exchange	10 to 10000

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3

Performing a Red Blood Cell Exchange (RBCX) Procedure

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RBCX Procedure Types

The Spectra Optia system can be used to perform the following types of Red Blood Cell Exchange (RBCX) procedures:

- Exchange
- Depletion/Exchange
- Depletion

During an exchange procedure, the system removes defective RBC from the patient and replaces them with healthy donor RBC. During a depletion procedure, the system removes excess or defective RBC from the patient and replaces them with desired replacement fluid. A depletion/exchange procedure consists of a depletion procedure followed by an exchange procedure.

Follow the instructions on the screens and in this chapter to select a Red Blood Cell exchange (RBCX) procedure and then the type of exchange you want to perform.

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Functional Description of an RBCX Procedure

There are three main phases of operation during an RBCX procedure: Centrifuge ramp phase, depletion phase and exchange phase. The centrifuge ramp phase occurs during each RBCX procedure. The type of procedure you select determines whether a depletion or an exchange phase occurs. The phases of operation begin after the system pumps the patient's blood into the channel of the tubing set at the start of the run.

Centrifuge ramp phase

During the centrifuge ramp phase, the system increases the centrifuge speed to the rpm required for removing RBC from the channel. This phase occurs at the start of the run, after the system decreases the speed or stops the centrifuge due to an operating condition or alarm, or any time a faster speed is required, such as after a significant increase in the inlet pump flow rate.

Depletion phase

The depletion phase occurs during a depletion or depletion/exchange procedure. During a depletion phase, RBC exit the channel to the remove bag. The system returns plasma and replacement fluid. This phase starts when the centrifuge ramp phase is complete and ends when the target Hct (depletion procedure) or minimum Hct (depletion/exchange procedure) has been attained.

Exchange phase

The exchange phase occurs during an exchange or depletion/exchange procedure. During an exchange phase, the RBC exit the channel to the remove bag and the system returns plasma and replacement RBC to the patient. This phase starts when the centrifuge ramp phase (exchange procedure) or initial depletion procedure (depletion/exchange procedure) is complete and ends when the target FCR (fraction of cells remaining) or target volume of replacement RBC has been attained.

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Preparing to Perform the Procedure

Supplies

Assemble the following supplies before you begin an RBCX procedure:

- Spectra Optia Apheresis System
- Spectra Optia Exchange Set
- 0.9% sodium chloride injection USP
- Anticoagulant ACD-A
- Replacement fluid prescribed by the patient's physician
- If using peripheral access:
  - Two needles of sufficient gauge to accommodate the procedure flow rate
  - Supplies for preparing the venipuncture site
  - Blood pressure cuff
- If using a vascular access device:
  - Supplies to disinfect, aspirate from, and connect to the device according to your standard operating procedures

Optional supplies:

- Filters for replacement fluid
- Supplies for collecting blood samples
- Apheresis procedure record

Selecting the Procedure

Perform the following steps to select an RBCX procedure. Then follow the steps on the screens and in this guide to enter the required patient and procedure data, and to select the type of RBCX procedure you want to perform.

1. Touch **Select Procedure**. The procedure selection screen appears.
2. Touch **Red Blood Cell Exchange (RBCX)**.
3. Touch **Confirm**. The system loads the procedure software and returns to the prepare procedure screen.

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Loading and Priming the Tubing Set

Follow the instructions on the screens and in the *Spectra Optia® Apheresis System Essentials Guide* to load, test, and prime the tubing set.

Navigating the RBCX Procedure Screens

Table 3–1 shows the menu buttons and menu tabs to use to navigate the screens during an RBCX procedure. Menu buttons and tabs are active depending on the current operating state.

Table 3–1: Menu buttons and tabs on RBCX procedure screens

Config	Data	Run	End Run
System	Patient Data	Exchange Status	Rinseback
Report	Fluid Data	Operation Status	Disconnect
RBCX	Alarm History	Bolus	Run Targets
Blood Warmer	Report	Strobe	
		Run Values	
		Options	

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Entering and Confirming Patient and Procedure Data

This section contains instructions for entering the patient data, selecting the exchange type, entering the fluid data, and entering and confirming the target values and run values. You can enter the data after you select the procedure and before you connect the patient.

Entering the Patient Data

Note: When you must enter numerical data, the system displays a data entry pad to enter the number. The acceptable numerical range appears on the data entry pad.

1. Touch the buttons on the screen to enter the following patient information:
   - Sex
   - Height
   - Weight
   - Hematocrit (Hct)
2. The Spectra Optia system uses the sex, height, and weight to calculate the patient's total blood volume (TBV), according to the formula described in Table 3–2. To change the TBV, touch **TBV** and enter a different volume.

   Note: The system cannot calculate an accurate TBV for patients that weigh less than 25 kg (approximately 55 lb).

   If the patient weighs less than 25 kg (approximately 55 lb), the system does not display a TBV. You must calculate and enter the appropriate TBV for the patient.
3. Touch **Confirm**. The fluid data screen appears.

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Table 3–2: Formula for calculating TBV (mL) using data in metric and English units

Metric		
	Female	183 + [356 x height^3 (meters)] + [33.1 x weight (kg)]
	Male	604 + [367 x height^3 (meters)] + [32.2 x weight (kg)]
English		
	Female	183 + [0.005835 x height^3 (inches)] + [15 x weight (lb)]
	Male	604 + [0.006012 x height^3 (inches)] + [14.6 x weight (lb)]

Source:

Allen TH, et. al. Prediction of blood volume and adiposity in man from body weight and cube of height. Metabolism 1959;39:307.

Nadler SB, et al. Prediction of blood volume in normal human adults. Surgery 1962;51:224-32.

Selecting the Exchange Type

The default exchange type is “Exchange” and appears on the button for the exchange type when the screen appears. To select a different exchange type, perform the following steps:

1. Touch **Exchange**. The following list of exchange types appears:
   - Exchange
   - Depletion/Exchange
   - Depletion
2. Select the exchange type by touching the corresponding button on the screen.

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Entering the Fluid Data

The fluid data buttons are enabled or disabled according to the exchange type you select. Perform the steps below to enter the fluid data and fluid balance.

Selecting the type of replacement fluid

Depletion:

1. Touch **Fluid Type**. A list of replacement fluid types to use for the depletion appears.
2. Select one of the following fluid types by touching the corresponding button on the screen:
   - Saline/Albumin
   - Plasma
   - Custom

Exchange:

1. Touch **Fluid Hct**. The data entry pad appears.
2. Enter the average Hct (%) of the replacement fluid for the exchange.

Note: The system uses data you enter, including the Hct of the replacement fluid, to determine when the target Hct has been attained. It is important that you enter an accurate Hct for the replacement fluid.

Entering the fluid balance

Note: The fluid balance includes fluid administered and removed during the entire procedure, but does not include fluid bolus volume.

1. The Spectra Optia system allows you to enter the fluid balance desired for the patient to have at the end of the procedure. To enter the fluid balance, do one of the following:
   - To enter an amount in mL, touch **Volume** and use the data entry pad to enter a negative or positive volume. The system will calculate and display the corresponding percent.
   - To enter an amount in percent, touch **Percent** and use the data entry pad to enter a percent. The system will calculate and display the corresponding volume.
2. Touch **Confirm** to save the fluid data. The run values screen appears.

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Entering and Confirming Run Targets and Run Values

Note: You may also access the run values screen by touching **View/Change Run Values** on the procedure data screen.

Enter the target values listed below, according to the type of RBCX procedure you selected. Table 3-3 contains descriptions of run targets that appear on the run values screens. Then review the run values on the screen and make any changes necessary to achieve your run targets.

Exchange procedures

- Target Hct (%)
- One of the following:
  - Replaced: Exchange (mL)
  - FCR (%)

Depletion/Exchange procedures

- Minimum Hct (%)
- Target Hct (%)
- One of the following:
  - Replaced: Exchange (mL)
  - FCR (%)

Depletion procedures

- Target Hct (%)

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Table 3-3: Descriptions of run targets for RBCX procedures

Run Target	Description
FCR (%)	Fraction of cells remaining. Desired percent of starting defective RBC remaining in the patient's blood at the end of the procedure. (Desired defective cells (%)/starting defective cells (%) = FCR.) After you enter an FCR for an exchange procedure, the system calculates and displays the volume of replacement fluid required to complete the procedure. **Note:** You may enter the starting and target defective RBC instead of the FCR, and the system will calculate and display the FCR. To do this touch the button for FCR on the screen and then touch **FCR** on the data entry pad. The icon appears on the data entry pad to indicate you have entered the values for defective RBC.
• Starting defective RBC (%)	Percent of defective RBC in the patient's blood at the start of the procedure
• Target defective RBC (%)	Percent of the defective RBC in the patient's blood at the end of the procedure
Minimum Hct (%)	Lowest patient Hct during the procedure.
Target Hct (%)	Desired patient Hct at the end of the procedure
Replaced (mL): Exchange	Volume of replacement fluid that is required to complete the exchange procedure. If you enter a volume here, the system calculates and displays the FCR.

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Perform the following steps to enter and confirm the run targets and run values:

1. Touch the button on the screen that corresponds to the target value you want to enter. The data entry pad appears.
2. Enter the target value.
3. Review the run values that appear on the screen to ensure that they are correct.

Note: During depletion/exchange procedures, the system displays the run time for the depletion in parenthesis above the total run time for the depletion/exchange.

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed will change back to white.

4. Touch **Confirm**.

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Starting the Procedure

1. Follow the instructions on the screen to perform the following steps:
   a. Empty the saline drip chamber.
   b. Rehang the saline container.
2. Touch **Confirm**.
3. If you are using a blood warmer on the replace line, perform the following steps to connect and prime the blood warmer tubing set, and prime the replace line:
   a. Disconnect the replace line from the spikes at the luer connector below the manifold.
   b. Clamp one end of the blood warmer tubing set.
   c. Connect the blood warmer tubing set to the spikes at the luer connector below the manifold.
   d. Spike the replacement fluid and squeeze the drip chamber.
   e. Unclamp the line to the second spike to prime both lines and fill the second drip chamber.
   f. Reclamp the line to the second spike.
   g. Unclamp the blood warmer tubing set and prime the tubing set.
   h. Reclamp the blood warmer tubing set.
   i. Connect the blood warmer tubing set to the luer connector on the replace line.
   j. Put the segment of the replace line that is between the manifold and the luer connector in the replacement fluid detector. The luer connector must be positioned below the replacement fluid detector.

   Note: Ensure that you position the luer connector below the replacement fluid detector. If the blood warmer tubing set is not positioned below the fluid detector, you must reprime the tubing set if the replacement fluid container runs dry during the procedure.
4. If you are not using a blood warmer on the replace line, perform the following steps to prime the replace line:
   a. Spike the replacement fluid and squeeze the drip chamber.
   b. Unclamp the second replace line to prime the lines and fill the second drip chamber.
   c. Reclamp the line to the second replace line.
   d. Put the replace line into the replacement fluid detector.
5. Touch **Continue**.

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6 Follow the instructions on the screen to do the following. Be sure to perform these steps in the order that appears on the screen:

a. If you are using a blood warmer on the return line, connect the blood warmer tubing set to the line.

b. Prime the inlet line and the return line. If you are using a blood warmer, prime the blood warmer tubing set.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

c. Clamp the inlet line and the and return line.

d. Close the inlet saline line and return saline line.

7 Touch **Confirm**. The connect patient screen appears.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions on the screen to perform the following steps:

a. Connect the patient.

b. Unclamp the inlet and return lines.

2 Touch **Start Run**. The system primes the replace line with replacement fluid, and then begins drawing the patient's blood into the tubing set. The main run screen appears.

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Monitoring the Run

This section contains descriptions of run screens that help you monitor the progress of the run. To access these screens, touch the **Run** menu button and then the tab for the screen you want to view. Ensure you verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and the bags.

Main Run Screen

The main run screen is the default run screen, and displays or provides access to the information that you are most likely to need to monitor the procedure. If you want to return to the main run screen after viewing a different screen during the run, touch the go back button, the active menu button, or the tab for the current screen. Figure 3-1 shows an example of the main run screen for a depletion/exchange procedure.

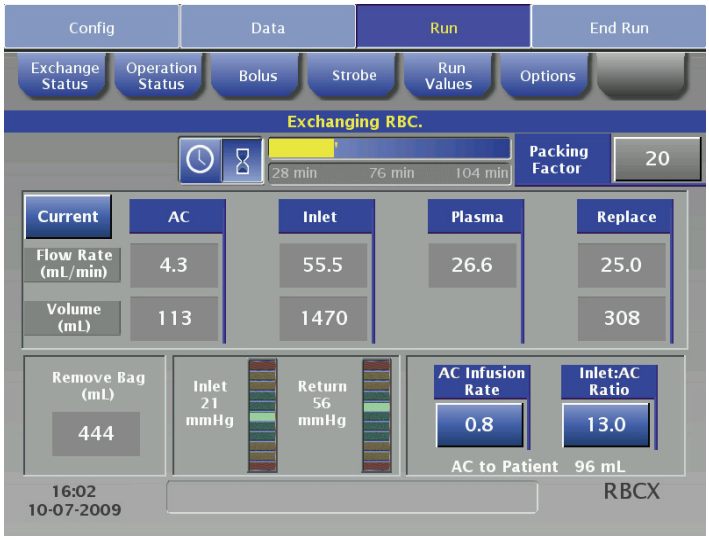

Figure 3-1: Example of the main run screen for a depletion/exchange procedure

Run time bar graph

Touch the hourglass icon to view the elapsed run time, the remaining run time, and the total run time. Touch the clock icon to view in clock time the starting run time, the current time, and the ending run time. If you are performing a depletion/exchange procedure, a yellow mark appears on the graph to indicate when the depletion phase will end.

Packing factor

Packing factor is a number that indicates how the system separates the blood in the channel to maintain a specific interface position in the connector. The current packing factor appears on the button.

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Current/target flow rate (mL/min) and volume (mL)

Touch **Current** or **Target** to toggle between the current and target views for flow rates and volumes for the AC, inlet, plasma, and replace pumps.

Remove bag (mL)

Remove bag (mL) indicates the current volume in the remove bag.

AC infusion rate

The maximum AC infusion rate (mL/min/L TBV) for the current procedure appears on the button. Touch this button to change the maximum rate (mL/min/L TBV) at which the AC from the ACD-A bag and the AC in the replacement fluid is infused to the patient.

Inlet:AC ratio

The ratio of inlet volume to AC from the ACD-A bag (__.1) for the current procedure appears on the button. Touch this button to change the inlet:AC ratio.

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Exchange Status Screen

To access the exchange status screen, touch the **Run** menu button and then touch the **Exchange Status** tab. This screen displays the current status of the exchange. Figure 3-2 shows an example of the exchange status screen for a depletion/exchange procedure.

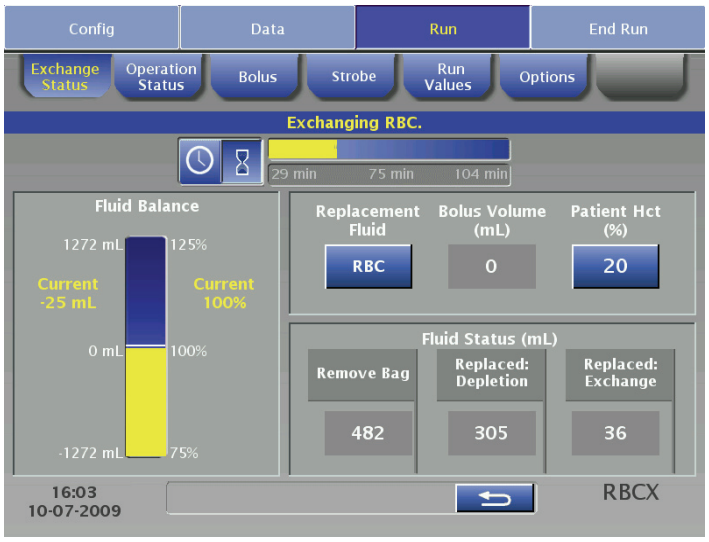

Figure 3-2: Example of the exchange status screen for a depletion/exchange procedure

Fluid balance

The graph shows the current patient fluid balance in volume (mL) and percent (%). The values at the top and bottom of the graph indicate the absolute fluid balance limits the system allows for this patient.

Replacement fluid

The type of replacement fluid currently in use appears on the button. Touch this button to select a different fluid type.

Bolus volume (mL)

Bolus volume (mL) is the cumulative volume of fluid bolus that has been given during the procedure.

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Patient Hct (%)

The current (estimated) patient Hct the system predicts appears on the button. Touch this button to change the value if it is necessary for you to remeasure the patient's Hct during the run.

Note: The system uses the patient Hct and the replacement fluid Hct that you enter before the start of the run to predict the current patient Hct. If the data entered is not correct, the prediction will not be accurate.

Fluid status (mL)

Fluid status (mL) shows the current volume in the remove bag and the volume of replacement fluid that has been used during the current procedure.

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Monitoring the Patient and Adjusting the Procedure

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the system.
2. Notify the attending physician of the patient's condition, according to your facility's standard operating procedures.
3. To reduce the symptoms and continue the run, touch **AC Infusion Rate** on the main run screen and reduce the rate to the desired value.
4. If reducing the infusion rate does not alleviate the symptoms, pause the procedure and administer appropriate medical treatment.

Giving a Fluid Bolus

Perform the following steps to give a fluid bolus:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Bolus** tab. The fluid bolus screen appears.
3. Follow the instructions on the screen to spike the saline container to the replace line. Confirm that the replace line is not clamped.
4. Touch **Volume** and enter the volume (mL) of the bolus.
5. Touch **Flow Rate** and enter the flow rate (mL/min) for the bolus.

Note: If the fluid you use for the bolus is a blood product, enter a flow rate in accordance with your local transfusion practices.

6. To begin the bolus, touch **Start Bolus**. The system delivers the bolus.

   The screen displays the progress of the bolus. To cancel the bolus before delivery is complete, touch **Cancel Bolus**.
7. When the bolus is complete, the system pauses. Touch **Continue** to resume the procedure.

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Changing the Type of Replacement Fluid

Perform the following steps to change the type of replacement fluid during the run:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Fluid Data** tab. The fluid data screen appears.

Note: To reach the fluid data screen from the exchange status screen, touch the button for replacement fluid.

3. Change the type of replacement fluid.
4. Touch **Confirm**.The run values screen appears.
5. Review the run values.
6. Touch **Confirm**.

Changing the Fluid Balance

Perform the following steps to change the fluid balance:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Fluid Data** tab. The fluid data screen appears.
3. Enter the new fluid balance.
4. Touch **Confirm**. The run values screen appears.
5. Review the run values.
6. Touch **Confirm**.

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Changing the Current Patient Hct

Perform the following steps to change the current patient Hct during the run:

1. Touch the pause button to pause the pumps.
2. Measure the patient's Hct, according to your standard operating procedures.
3. Touch the **Run** menu button. The run tabs appear.
4. Touch the **Exchange Status** tab. The exchange status screen appears.
5. Touch the button for the patient Hct. The data entry pad appears.
6. Enter the current patient Hct. A screen appears to confirm the change to the Hct.
7. Follow the instructions on the screen to verify and confirm the change. The run values screen appears.
8. Review the run values.
9. Touch **Confirm**.
10. Touch the pause button to restart the pumps.

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Discontinuing or Ending the Run

Discontinuing the Run

If you decide to discontinue the run before attaining a run target, perform the following steps:

1 Touch the **End Run** menu button.

2 Do one of the following:

- To discontinue the run, touch the **Disconnect** tab and follow the instructions under "Completing the Procedure" on page 39 to complete the procedure.
- To discontinue the run and perform rinseback, touch the **Rinseback** tab and follow the instructions under "Ending the Run With Rinseback" on page 38 to complete the procedure.

Ending the Run

The run targets screen appears and the system sounds a tone when a run target has been attained. Review the run targets and decide to extend or end the run. Figure 3-3 shows and example of a run targets attained screen for a depletion/exchange procedure.

Figure 3-3: Example of a run targets attained screen for a depletion/exchange procedure

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Extending the Run

1. To extend the run, increase the value of a run target. Touch the button for the run target you want to increase and use the data entry pad to enter a new value. The run values screen appears.
2. Review the run values.
3. Touch **Confirm**. The system will continue the run. When the new target is attained, the run targets attained screen reappears and the system sounds a tone.

Ending the Run

1. Touch **Disconnect**. The confirm disconnect screen appears.
2. Touch **Proceed to Disconnect**, and then touch **Confirm**.

Ending the Run With Rinseback

Warning: Terumo BCT does not recommend performing rinseback during RBCX procedures. The data the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

1. Touch the **End Run** menu button. The end run tabs appear.
2. Touch the **Rinseback** tab. The confirm rinseback screen appears.
3. Touch **Proceed to Rinseback,** and then touch **Confirm**.
4. Follow the instructions on the screen to clamp the inlet line.
5. Touch **Continue**. The system tests the pressure in the inlet line.
6. Follow the instructions on the screen to open the inlet saline line.
7. Touch **Continue**. The rinseback status screen appears.

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Completing the Procedure

This section provides instructions on disconnecting the patient and reviewing the procedure summary data. For instructions on printing a copy of a procedure report, see the *Spectra Optia® Apheresis System Essentials Guide.*

Disconnecting the Patient

1. Follow the instructions on the screen to perform the following steps:
   a. Clamp the inlet line and return line.
   b. Disconnect the patient lines.
   c. Seal the AC line, saline line, and lines to the bags.
2. Touch **Unload**. The system confirms that the inlet and return lines are clamped, and raises the cassette. The procedure summary screen appears.

Reviewing the Procedure Summary Data

The procedure summary screens contain important data about the procedure. The screens appear at the end of the procedure after the cassette is raised. Figures 3-4 and 3-5 show example pages of the procedure summary screens. Tables 3–4 and 3–5 contain descriptions of the data that can appear on the screens.

Note: The start time and end time on the procedure summary screen are accurate to ± 1 minute.

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Procedure Summary, Page 1

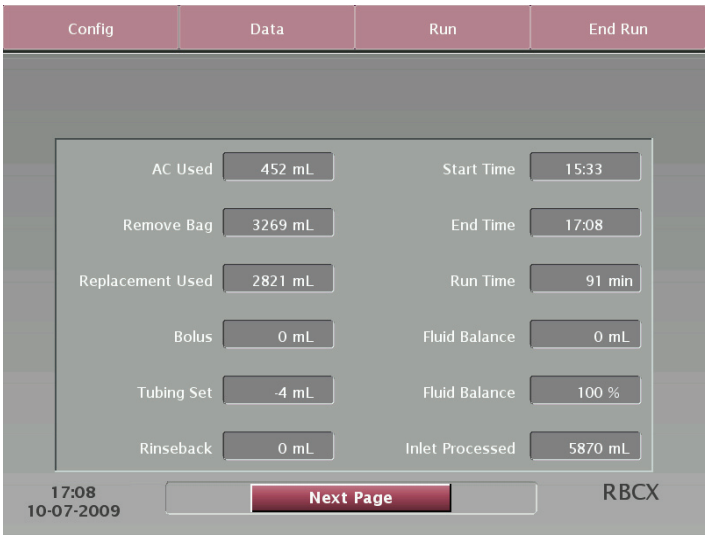

Figure 3-4: Example of page 1 of the procedure summary for all RBCX procedures

Table 3–4: Descriptions of data on page 1 of the RBCX procedure summary screens

Data	Description
AC Used	Total volume of AC used during the run
Remove Bag	Total volume of saline, AC, and blood in the remove bag
Replacement Used	Total volume of fluid the replace pump processed, not including any bolus volume
Bolus	Total volume of fluid delivered to the patient during the bolus
Tubing Set	Difference between the volume in the tubing set at the start of the run and the volume in the set at the end of the run or at the start of rinseback (negative value indicates fluid volume in the set)
Rinseback	Total volume of fluid the return pump processed during rinseback, not including any bolus volume given during rinseback
Start Time	Time when the operator touched **Start Run**
End Time	Time when the system completed the run or rinseback
Run Time	Total time the system operated the inlet pump (does not include time when the pump was paused)

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Table 3–4: Descriptions of data on page 1 of the RBCX procedure summary screens (continued)

Data	Description
Fluid Balance	Patient fluid balance (mL) at the end of the procedure (does not include fluid bolus volume)
Fluid Balance	Patient fluid balance (%) at the end of the procedure (does not include fluid bolus volume)
Inlet Processed	Total volume of fluid (includes Whole Blood and AC) the inlet pump processed during the run

Procedure Summary, Page 2

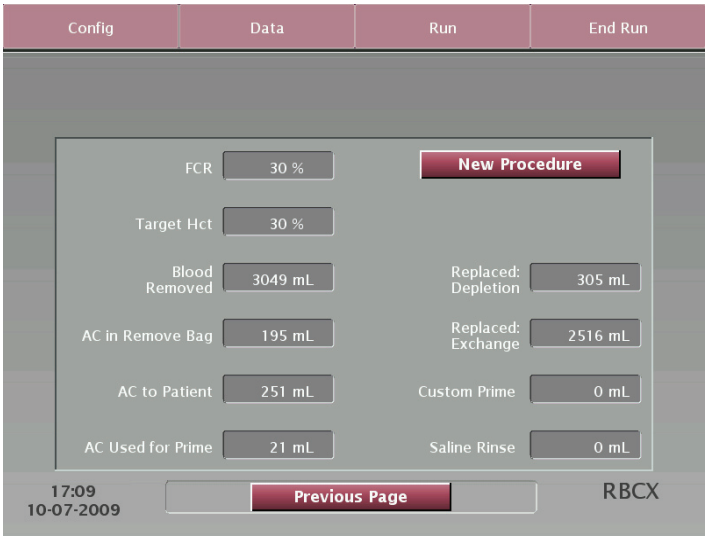

Figure 3-5: Example of page 2 of the procedure summary for a depletion/exchange procedure

Table 3–5: Descriptions of data on page 2 of the RBCX procedure summary screens

Data	Description
FCR	Percent of starting defective RBC remaining in the patient's blood
Target Hct	Predicted patient Hct at the end of the procedure
Blood Removed	Total volume of patient blood removed
AC in Remove Bag	Total volume of AC (from AC bag) in the remove bag
AC to Patient	Total volume of AC (from AC bag) the patient received
AC Used for Prime	Volume of AC (from AC bag) used for the saline prime

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Table 3–5: Descriptions of data on page 2 of the RBCX procedure summary screens

Data	Description
Replaced: Depletion	Total volume of replacement fluid used during the depletion
Replaced: Exchange	Total volume of replacement fluid used during the exchange
Custom Prime	Total volume of fluid used for the custom prime
Saline Rinse	Total volume of saline used for the saline rinse

Starting a New Procedure

Unload the tubing set according to the instructions in the *Spectra Optia® Apheresis System Essentials Guide*, and then touch **New Procedure** on page 2 of the procedure summary. The system resets, so that you can select your next procedure.

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Red Blood Cell Exchange (RBCX) Procedure Guide

Spectra Optia®

Apheresis System

RBCX

TERUMOBCT
Unlocking the Potential of Blood

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Attachment F
Updated Spectra Optia System Essentials Guide

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Spectra Optia®

Apheresis System

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ESSENTIALS

Essentials Guide

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Spectra Optia® Apheresis System

Essentials Guide

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United States: 5674173, 5676644, 5676645, 5722926, 5734464, 5795317, 5824881, 5906570, 5913768, 5919154, 5921950, 5936714, 5939319, 5941842, 5951877, 6053856, 6071422, 6200287, 6234989, 6280406, 6334842, 6361518, 6409696, 6497674, 6514189, 6730055, 6764460, 6773413, 6790195, 6899691, 6945948, 7029430, 7108672, 7169352, 7327443, 7354415, 7355685, 7422693, 7513882, 7549956, 7556611, 7605388, 7608053, 7671975, 7704454, 7780618, 7824355, 7828709, 7906771, 7943916, 7951059, 8057376, 8062202, 8066888, 8070663, 8088090, 8241196, 8337379, 8449439
and counterpart foreign patents:
Canada: 2527667
France: 2207023
Germany: 60035474.1, 60036906.4, 60041426.4, 60044623.9, 60044624.7, 60145279.8, 69618453.2, 69634860.8, 69636518.9, 69637310.6, 69637706.3, 69638219.9, 69638403.5, 69733198.9, 69739552.9, 69820404.2, 69836648.4, 69840459.9, 69842455.7, 602004027910.2, 602008010061.8. 602004041451.4
Great Britain: 2220477
Japan: 4099240, 4194667, 4304264, 4331204, 4382322, 4425938, 4459263, 4536806, 4746055, 4771595, 4886004, 5209737
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Preface

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About This Guide

This guide is one of several guides that comprise the Spectra Optia Apheresis System operator's manual. It contains information and instructions on how to safely operate, transport, troubleshoot, and maintain the Spectra Optia system and the Seal Safe system. You should read and understand the information in this guide before operating the system. Use this guide in conjunction with the appropriate Spectra Optia Apheresis System procedure guide when performing a procedure on the system.

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Conventions Used in this Manual

This operator's manual uses certain conventions to help you identify the tasks that you must perform. This section describes these conventions.

Numbered Steps

All step-by-step instructions are numbered and the numbers appear in bold, as shown in the following example:

1 Carefully unpack the system from the shipping container.

Touch screen buttons

Many of the steps instruct you to touch a button on the screen. The text on the button appears in bold, as shown in the following example:

1 Touch **Confirm**.

Bullets

Bullets (•) are used to indicate items in a list.

Warnings, Cautions, and Notes

The following examples show how warnings, cautions, and notes appear in this document:

Warning: Warnings alert the operator of serious hazards, consequences, or conditions that are likely to result in a harmful reaction, trauma, or death to the patient or operator.

Caution: Cautions alert the operator to the possibility of a problem with the device associated with its use or misuse. This includes device malfunction, failure, and damage to the device or other property.

Note: Notes emphasize important details.

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Spectra Optia Apheresis System

Intended Use

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications and cell collections. Refer to the Spectra Optia Apheresis System procedure guides for information about using the system to perform specific procedures.

Contraindications for Use

There are no known contraindications for the use of the Spectra Optia system except those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

Warnings and Cautions for Use

Below is a complete list of warnings and cautions that apply to the use of the Spectra Optia system and the Seal Safe system. Although the information may also appear in other sections of this guide, the operator should read and understand the information in this list before using the system.

Some of the warnings or cautions may instruct you to contact Terumo BCT. Customers in the U.S. should contact Terumo BCT Customer Support. Customers outside the U.S. should contact their local Terumo BCT representative.

Warnings for Use

System warnings

1. DANGER: Do not use the Spectra Optia system in an explosive atmosphere.
2. To avoid possible patient injury or loss of life, use only operating procedures published by Terumo BCT.
3. Terumo BCT will not be responsible for patient safety if the procedures to operate the Spectra Optia system are other than those specified by Terumo BCT. Individuals performing the procedures must be appropriately trained and qualified.
4. Use only the filler and the tubing sets that Terumo BCT manufactures for the Spectra Optia system.
5. The manufacturer, assembler, installer, or importer regards itself as responsible for effects on the safety, reliability, and performance of the device, only if the device is employed in accordance with the instructions for use.

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6 The Spectra Optia system can interfere with EKG monitoring when a patient is simultaneously undergoing apheresis and EKG monitoring.

7 The Spectra Optia system alarms are inactive when the system is turned off.

Service warnings

8 To avoid possible patient injury or loss of life, use only maintenance procedures published by Terumo BCT.

9 Terumo BCT will not be responsible for patient safety if the procedures to maintain and calibrate the Spectra Optia system are other than those specified by Terumo BCT. Individuals performing the procedures must be appropriately trained and qualified.

10 Only a qualified service representative should perform equipment modifications. Any modifications must be approved in writing by Terumo BCT.

11 Turn off the system before cleaning to prevent possible electrical shock or damage to the equipment.

12 Unplug the system from the power supply before servicing.

13 Only a qualified service representative should service or repair the Spectra Optia system.

14 When cleaning and disinfecting equipment surfaces that might have been exposed to blood, take adequate precautions to prevent possible exposure to and transmission of infectious diseases.

Electrical warnings

15 All electrical installations must comply with all applicable local electrical codes and Terumo BCT's specifications.

16 To reduce the risk of electric shock do not use alternate power plugs or adapters that disconnect the green wire safety ground.

17 Non-medical electrical equipment connected to the Ethernet connection should not be located within the patient environment. The definition of "patient environment" can be found in the IEC standard 60601-1-1, 2.202.

18 Accessory equipment connected to the analog and digital interfaces must be certified according to applicable IEC standards (e.g., IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all system configurations shall comply with the system standard IEC 601-1-1. The installer of accessory equipment is responsible for the integrated medical system compliance with requirements of IEC 601-1-1. If you are in doubt, contact your Terumo BCT service representative.

Procedural warnings

19 Do not connect the patient before the system instructs you to do so.

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20 Rigorous attention should be paid to proper venipuncture site selection and decontamination.

21 It is advisable to obtain the patient's detailed drug history before each apheresis procedure. For those drugs potentially affected by apheresis procedures, the physician should either adjust the doses or give the medications immediately after the procedure.

22 Tubing sets manufactured by Terumo BCT contain DEHP. Results from selected studies of rodents exposed to DEHP (typically via an oral route) have shown potentially harmful effects to male reproductive organs during fetal development. Because of this, patient groups that include pregnant or nursing women and children are considered to be most at risk to potential harmful effects of exposure to DEHP. However, no studies performed to-date involving other mammals and humans exposed to intravenous DEHP have shown similar results. Regulatory bodies have noted that the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP. It is the responsibility of treating physicians to balance this risk for their patients.

23 The operator must verify the correct input of information relevant to the safety of each apheresis procedure.

24 When preparing to perform a procedure, ensure that the lines are connected to the correct fluids, and that fluid is flowing into the drip chambers:

- AC line (orange) to the anticoagulant container
- Saline line (green) to the normal saline (0.9%) container

25 Check that the tubing is correctly loaded in all pumps before starting a procedure. Visually inspect each pump to ensure that tubing does not protrude.

26 Before starting a procedure, inspect all lines, especially those in the centrifuge and on the front panel to ensure they are not obstructed. Tubing that is occluded or mechanically constrained can lead to malfunction or fluid imbalance. Inlet and return lines perform without difficulty as long as the interior diameter of the tubing is larger than the interior diameter of the patient's inlet and return access.

27 Only blood or blood products should be processed in the centrifuge.

28 If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

29 When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

30 Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

31 Monitor the return line for air. If you see air in the line, go to the operation status screen, touch **Remove Air From Return Line**, and follow the instructions on the screen.

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32 Before connecting the patient, ensure that the AC line contains anticoagulant at the inlet manifold.

33 The inlet and return pressure sensors are not intended to detect infiltrations of the vein. Monitor the patient for infiltrations.

34 Tubing sets may occasionally fail, which could result in the loss of blood, blood products, or the introduction of air into the tubing set. It is very important that the operator watch for leaks in the cassette, all tubing and welds, and in the channel while the set is in use. Operators should take adequate precautions in handling blood and blood products in accordance with their facility's standard operating procedures.

35 When handling extracorporeal blood circuits, take adequate precautions to prevent the possible exposure to and transmission of infectious diseases.

36 The following can cause fluid imbalance:

- Administration of replacement fluid that is not at room temperature during a procedure
- Use of improperly vented fluid containers
- Equipment malfunction
- Improperly clamped or closed lines, or improperly loaded valves
- Use of inadequately primed or clotted filters on the replace line of the Exchange Set
- Tubing that is incorrectly loaded in the pumps

37 The alarm system is inactive during a manual rinseback. If you must perform a manual rinseback, watch for air in the return line. If you see air, immediately discontinue the rinseback.

38 Do not apply excess pressure to the vent bag when pushing fluid from the reservoir to the patient during a manual rinseback or you could damage the Red Blood Cells that you are returning to the patient.

39 Do not continue to squeeze the vent bag after the fluid in the reservoir reaches the level of the reservoir filter during a manual rinseback. If you continue to squeeze the bag, you could deliver air to the patient.

40 Do not touch **Unload** to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

41 All used disposable materials should be considered hazardous, and should be handled and disposed of at the end of the procedure in accordance with all applicable regulations.

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Solution and medicinal fluid warnings

42 When using biologically-derived replacement fluids, closely monitor the patient for reactions.

43 Use only 0.9% sodium chloride solution for procedures performed on the Spectra Optia system. Using a solution with a different composition could cause hemolysis.

Seal Safe system warnings

44 Use only the sealer head and radio frequency (RF) cable provided by Terumo BCT with the Seal Safe system. The Seal Safe system does not function correctly with components from other tubing sealers.

45 Do not seal the tubing within 8 cm (3 in) of the needle, or you may cause a burn at the needle entry point.

46 Do not place your fingers within 2.5 cm (1 in) of the Seal Safe system's sealing jaw, or you may receive a radio frequency (RF) burn.

47 Do not release the lever of the sealer head until after the indication light goes out. Releasing the lever sooner could result in an inadequate seal.

48 Ensure that the sealer head and the tubing are free of moisture and debris before using the Seal Safe system.

49 Moisture on the surface of the tubing or the sealer head may cause an electrical arc to occur between the jaws when the power is applied, terminating the sealing process. If an arc occurs, carefully inspect the seal to ensure it is satisfactory.

50 Ensure that there is no tension on the tubing when operating the Seal Safe system. Stretching the hot tubing could cause a leak.

51 Do not submerge the Seal Safe system in liquid or you may receive an electric shock.

52 Disconnect the sealer head from the RF cable before cleaning to avoid receiving a serious radio frequency (RF) burn during the cleaning process.

53 The jaw on the sealer head contains an indentation where the spring rests. If you do not properly seat the spring in the indentation after cleaning, you may damage the spring, which could cause inadequate tubing seals.

54 Do not open the sealer head to service the device or you may receive an electric shock. Contact a qualified service representative to service the device.

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Cautions for Use

System cautions

1. Use of the Spectra Optia system is restricted to prescription only.
2. Each operator should be thoroughly familiar with the Spectra Optia system's operating instructions before using the system. All procedures should be performed by qualified medical personnel under the supervision of a physician.

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3 The Spectra Optia system and the Seal Safe system comply with all relevant international standards concerning electromagnetic emissions and compatibility. Before undergoing apheresis, patients with active implantable medical devices should review the implant manufacturer's instructions for any cautions or contraindications concerning the use of and/or proximity to devices that emit electromagnetic energy. Examples of active implantable devices include cardiac pacemakers and cardioverter defibrillators, cochlear implants, vagus nerve stimulators, and devices that stimulate the peripheral or central nervous systems. This caution also extends to other devices that may connected to the patient such as ECG equipment and infusion systems. Care should be taken to prevent the Seal Safe system from touching the patient or any cables of the devices that may be connected to the patient.

4 Do not use the Spectra Optia system under any of the following conditions:

- Power cords, plugs, or receptacles are damaged or worn.
- Switches are loose.
- System has received a physical shock, or liquid has spilled on the electronics housed under the cover.
- Anyone has received an electrical shock while using the system.
- System appears to be overheating.

5 Keep hair, fingers, clothing, and other articles away from pumps and valves to avoid entanglement.

6 Do not put open containers containing fluid on the device. Fluid spills can contribute to electrical and mechanical hazards.

7 To avoid damage to the Spectra Optia system, do not operate the centrifuge without a filler installed or before loading the channel.

8 Before installing a filler or loading a tubing set, inspect the filler and visible interior of the centrifuge chamber for fluid spills or structural damage. Ensure the metal band around the perimeter of the filler is centered and secure.

9 To avoid damage to the centrifuge and the filler, do not operate the centrifuge if the filler latch is not lowered and locked in place. Ensure that the filler cannot be pulled off the gear train without unlocking and raising the filler latch.

10 To avoid personal injury or damage to the system, use proper lifting techniques when lifting the Spectra Optia system.

11 Ensure that the wheel pedal is pressed to the right (locked) position during procedures, so that the Spectra Optia system does not move.

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12 In the event of a prolonged power interruption, the use of an uninterruptible power supply (UPS) may allow the operator to discontinue the procedure and perform rinseback. However, a UPS does not ensure that the operator can complete the procedure as intended.

Service cautions

13 Clean the Spectra Optia system using a mild cleaning solution, or a mild detergent. Industry standard practice defines mild detergent as a solution or detergent that is safe on skin and on washable surfaces, such as hand dishwashing liquid. Use of a solution that is not compatible with the materials on the system may damage the material or operating characteristics of the system.

14 Disinfect the Spectra Optia system using a 0.25% sodium hypochlorite (bleach) solution. Use of a stronger bleach solution may damage or discolor the system.

15 To avoid scratching the Spectra Optia system touch screen or the glass covers on the lights inside the centrifuge, do not clean the screen or covers with an abrasive brush or scrub material.

16 Do not use alcohol or alcohol-based products to clean the touch screen to avoid damaging the screen's surface.

17 Do not spray or douse the Red Blood Cell (RBC) detector with liquid to clean it. Using an excessive amount of liquid can damage the detector. If you must spray the front panel, cover the RBC detector beforehand.

18 Terumo BCT has validated the methods described in this manual for cleaning and decontaminating the Spectra Optia system. Before using an alternative method, verify that it will not damage the system.

19 Do not lubricate pumps or pump rotors for any reason.

Procedural cautions

20 The Spectra Optia system has many safety features. However, a patient reaction can occur rapidly. Therefore, it is imperative that the operator monitor the patient and the system throughout the procedure.

21 The physiological condition of patients may affect the outcomes of procedures performed on the Spectra Optia system.

22 Patients with impaired or abnormal citrate metabolism (for example, if the patient has liver or renal disease) may present an increased risk of citrate sensitivity. Attending physicians should assess the appropriateness of such patients for apheresis procedures and prescribe how they should be monitored during procedures.

23 Use aseptic technique throughout all procedures to ensure patient safety.

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24 Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit.

25 The higher the inlet:AC ratio used during the procedure, the greater the risk is for platelet aggregates and clots to form in the tubing set.

26 For patient comfort and optimal system operation, ensure that the fluids used during the procedure are at room temperature before connecting them to the tubing set.

27 Do not connect the fluids to the tubing set before the system instructs you to do so.

28 To avoid a failed test of the tubing set, do not raise and lower the cassette after there is fluid in the set.

29 Follow local transfusion practices when performing a custom prime.

30 If you leave the roller clamp on the saline line completely open when the patient is connected, you will quickly infuse a large volume of saline to the patient.

General tubing set cautions

31 **Not for Reuse**: Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.

32 The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:

- Severe kinks in the tubing are apparent.
- Tubing set appears to be incorrectly assembled.
- Tubing set is damaged.
- Any clamps are closed on the lines.

33 You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.

34 Do not stretch the tubing when folding the channel to install it in the centrifuge to avoid damaging the tubing set.

35 Use only your fingers to load the channel into the filler. To avoid puncturing the channel, never use a sharp object.

36 Do not seal the inlet line of the four-lumen tubing. Sealing the line could cause the tubing set to fail when you raise the cassette to unload the set.

37 Ensure all luer connections are secure.

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Exchange Set cautions

38 Do not use the Exchange Set if the end caps are not in place.

39 Leave the cap on the unused luer (on the remove bag) to prevent fluid leakage. Ensure the cap fits tightly.

Collection Set cautions

40 The Collection Set is no longer considered functionally closed if any of the following conditions are true:

- Inlet needle is not connected, or the end caps on the lines of the tubing set are missing when you open the package.
- First attempt to insert the inlet needle fails (unless you attach a new needle using a connection device that maintains the sterility of the tubing set).
- Inlet needle is disconnected during the procedure.
- If using the diversion bag to collect a blood sample, the sample is taken before the line to the bag is sealed.
- Any product bag or the diversion bag is disconnected before the line to the bag is sealed.
- Product sample is removed from the sample bulb before you permanently seal the line.
- Sterile barrier filters are damaged.
- Integrity of the tubing set is compromised for any reason.

41 To correctly lock the needle protector over the inlet needle, you must hold it in place while you pull the tubing to remove the needle. It will not lock if you use the wings of the needle or the body of the needle protector to remove the needle. After use, visually confirm that the needle protector is locked over the needle and that the wings are secured behind the locked prongs.

Seal Safe system cautions

42 The Spectra Optia system and the Seal Safe system comply with all relevant international standards concerning electromagnetic emissions and compatibility. Before undergoing apheresis, patients with active implantable medical devices should review the implant manufacturer's instructions for any cautions or contraindications concerning the use of and/or proximity to devices that emit electromagnetic energy. Examples of active implantable devices include cardiac pacemakers and cardioverter defibrillators, cochlear implants, vagus nerve stimulators, and devices that stimulate the peripheral or central nervous systems. This caution also extends to other devices that may connected to the

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patient such as ECG equipment and infusion systems. Care should be taken to prevent the Seal Safe system from touching the patient or any cables of the devices that may be connected to the patient.

43 Use the Seal Safe system only on tubing distributed by Terumo BCT. The Seal Safe system may not perform as expected on other tubing.

44 To avoid possible damage to the Seal Safe system, always disconnect the sealer head and the RF cable before transporting the Spectra Optia system.

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Service Information

Terumo BCT and/or its subsidiaries will not be responsible for the safety, reliability, or performance of this equipment unless:

- Operational procedures, calibration, and repairs are carried out by appropriately qualified persons.
- All equipment modifications are authorized in writing by Terumo BCT and performed by appropriately qualified persons.
- The electrical installation of the relevant room complies with all applicable local electrical codes and IEC requirements.
- The equipment is used in accordance with the published instructions for use.

Detailed service information for this equipment, including schematic diagrams and recommended service procedures, is available from your Terumo BCT representative.

Special Use of Additional Equipment and Devices During Apheresis Procedures

You may require one or more of the following items to complete an apheresis procedure using the Spectra Optia system:

- Blood/fluid warmer
- Solutions and medicinal fluids

For instructions on safely using additional items with the Spectra Optia system, refer to the guidelines provided by the equipment or device manufacturer.

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Solutions and Medicinal Fluids Administered During Apheresis Procedures

This section includes descriptions of solutions and medicinal fluids that may be used during apheresis procedures on the Spectra Optia system.

Saline Solution

Use sterile 0.9% sodium chloride solution to prime the tubing set and to perform the procedure.

Anticoagulant

ACD-A

Each 100 mL of ACD-A contains 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous.

Citrate toxicity

ACD-A can cause citrate toxicity in certain patients. Mild forms of this condition are generally recognized by peripheral paresthesia, tingling sensations in the extremities, and/or restlessness. Severe forms of this condition can result in significant cardiac dysfunction. Terumo BCT recommends that you frequently assess the condition of the patient throughout the apheresis procedure.

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Adverse Effects of Apheresis Procedures

Be aware of possible patient reactions to apheresis procedures, and be prepared to take appropriate action should any reactions occur. Some previously reported reactions are:

- Anxiety
- Headache
- Light-headedness
- Digit and/or facial paresthesia
- Fever
- Chills
- Hematoma
- Hyperventilation
- Nausea and vomiting
- Syncope (fainting)
- Urticaria
- Hypotension
- Allergic reactions

Reactions to Blood Products Used for a Custom Prime

Reactions to transfused blood products can include fever, circulatory overload, shock, allergic reactions, alloimmunization, and Graft-vs.-Host disease, as well as transmission of infectious diseases and bacteria. (Sources: *Circular of Information for the Use of Human Blood and Blood Components*, AABB, et al, ed., April, 2006; *Guide to the preparation, use and quality assurance of blood components*, 10th Edition, Council of Europe Publishing.)

Disposal of Infectious and Non-Infectious Waste

Follow your local regulations for disposing of material that may be contaminated with biohazardous products.

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2

Introduction

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Spectra Optia System Description

The Spectra Optia Apheresis System is a transportable, automatic blood component separator that uses centrifugation and optical detection (automated interface management system or AIM system) to perform therapeutic apheresis procedures.

The Spectra Optia system's touch screen interface enables the operator to communicate with the system. The operator follows the instructions on the screen to enter patient and procedure data, load and prime the tubing set, and perform and troubleshoot procedures. The system displays detailed information about the procedure, so that the operator can adjust the run values to achieve a specific outcome, or troubleshoot a condition. After the procedure is complete, the system provides a report of procedure data for the patient record.

Spectra Optia System Components

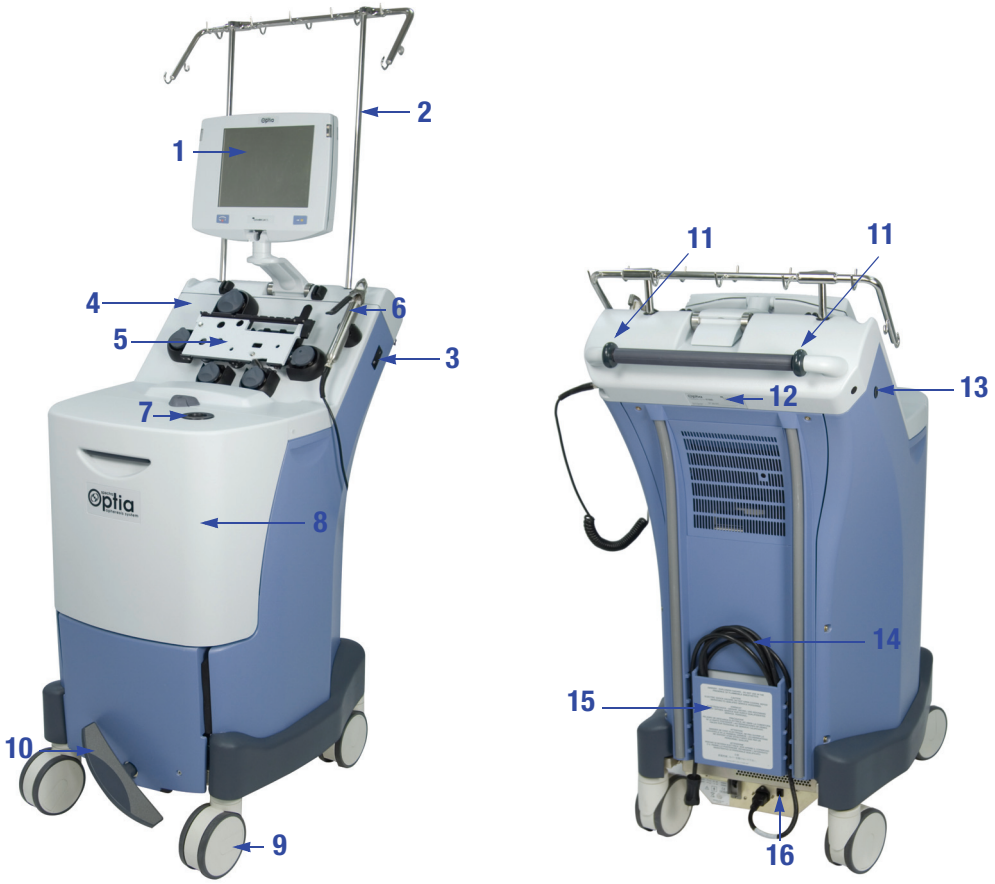

Figure 2-1: Spectra Optia Apheresis System front and back views

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Table 2-1: Spectra Optia system components

	Component	Function
1	Monitor with touch screen	Allows you to communicate with the system.
2	Dual IV pole	Has hooks for hanging bags and containers. You can adjust the height of the pole for transporting the device, or to hang and remove bags.
3	Power switch	Allows you to turn power to the system on and off.
4	Front panel	Holds the pumps, valves, sensors, and detectors.
5	Cassette tray	Holds the tubing set cassette in place.
6	Seal Safe system	Seals the lines of the tubing set.
7	View port	Allows you to look through the centrifuge door to see the interface in the channel.
8	Centrifuge door	Allows access to the centrifuge chamber.
9	Wheels	Used to transport the system.
10	Wheel pedal	Allows you to adjust the direction of the wheels for moving the system, or lock the wheels in place so that the system does not roll.
11	Handle wheels	Used to facilitate transport of the system in a horizontal position.
12	System serial number	Unique number used to identify the system.
13	IV pole release button	Allows you to lower the IV pole by pressing the button.
14	Power cord	Connects the system to a power source.
15	Power cord holder	Secures the power cord during transport.
16	Ethernet connection	Allows you to connect the system to a printer or a computer to print a procedure report.
17	Accessory bracket (not shown)	Can be used to hold an additional device used during an apheresis procedure, such as a blood warmer or an infusion pump.

Front Panel

The front panel of the Spectra Optia system holds the pumps, sensors, and valves that are used to perform an apheresis procedure. The locations of the components are shown in Figure 2-2,

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and the functions are described in Tables 2-2 through 2-4.

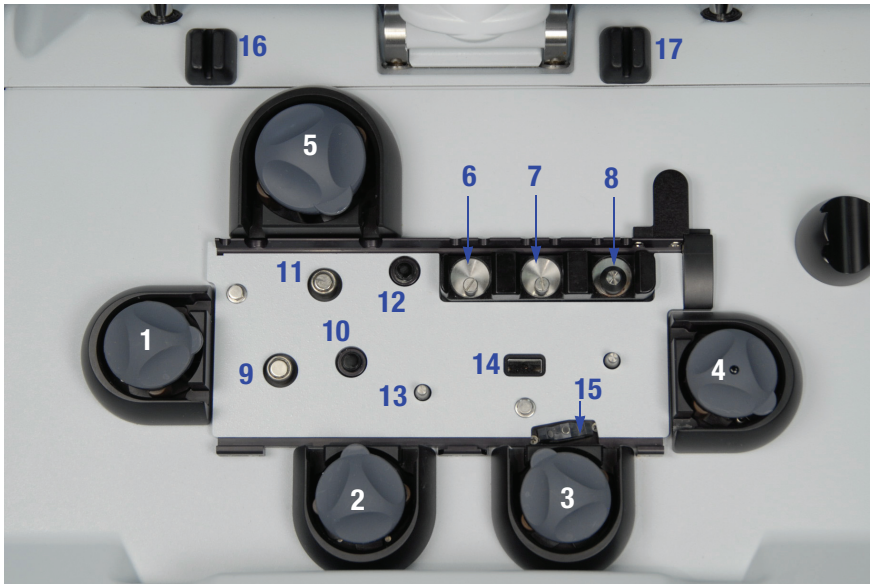

Figure 2-2: Front panel components

Pumps

Table 2-2: Functions of the Spectra Optia system pumps

	Pump	Function
1	Anticoagulant (AC) pump	Pumps anticoagulant from the AC container to the inlet line.
2	Inlet pump	Pumps anticoagulated blood from the patient to the channel.
3	Plasma pump	Pumps Plasma out of the channel.
4	Replace pump (Exchange) Collect pump (Collection) (black dot on the pump rotor)	Exchange procedures: Pumps replacement fluid out of the fluid container. Collection procedures: Pumps the collected component out of the channel or chamber.
5	Return pump	Pumps the contents of the reservoir to the patient.

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Valves

Table 2-3: Functions of the Spectra Optia system valves

	Valve	Function
6	Red Blood Cell (RBC) valve	Directs the flow of Red Blood Cells from the channel.
7	Plasma valve	Directs the flow of Plasma from the channel.
8	Remove valve (Exchange) Collect valve (Collection)	Directs the flow of the separated blood components from the channel.

Sensors and detectors

Table 2-4: Functions of the Spectra Optia system sensors and detectors

	Sensor/Detector	Function
9	Inlet pressure sensor	Monitors negative pressure in the inlet line to ensure that adequate inlet pressure is maintained.
10	Low-level reservoir sensor	Monitors the volume of fluid in the reservoir, and ensures that air does not enter the return line.
11	Return pressure sensor	Monitors positive pressure in the return line to ensure that the correct level of return pressure is not exceeded.
12	High-level reservoir sensor	Monitors the volume of fluid in the reservoir to help control the volume of fluid in the system.
13	Centrifuge pressure sensor	Monitors pressure in the channel and lines in the centrifuge to ensure that the correct level of pressure is not exceeded.
14	Bar code reader	Reads the tubing set identification number on the cassette to ensure that the correct tubing set is loaded for the procedure selected.
15	Red Blood Cell (RBC) detector	Exchange procedures: Detects Red Blood Cells in the Plasma line. Collection procedures: Detects Red Blood Cells in the collect line.
16	Anticoagulant (AC) fluid detector	Detects fluid in the AC line. Signals the system if the line contains air instead of fluid.
17	Replacement fluid detector	Detects fluid in the replace line during exchange procedures. Signals the system if the line contains air instead of fluid.

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Centrifuge Chamber

The Spectra Optia system centrifuge spins to create a centrifugal force that separates the blood into cellular components. The centrifuge chamber houses the centrifuge and the system components, as shown in Figure 2-3 and described in Table 2-3.

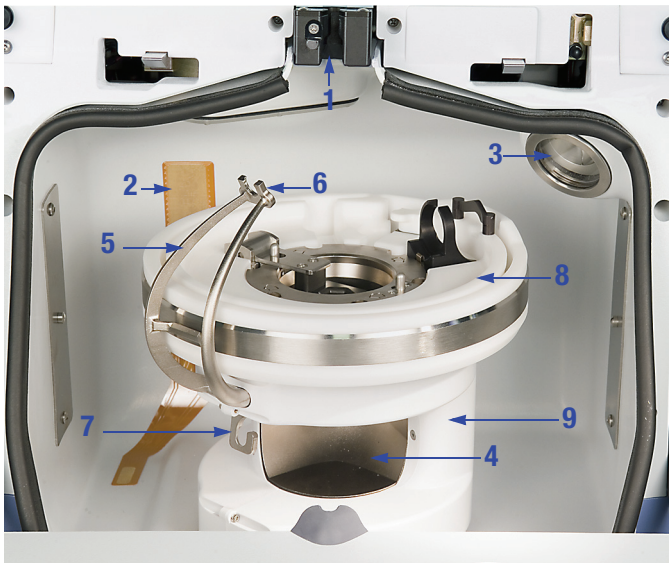

Figure 2-3: Centrifuge chamber components

Table 2-5: Functions of the Spectra Optia system centrifuge chamber components

	Component	Function
1	Upper collar holder	Secures the upper collar at the entrance to the centrifuge chamber.
2	Fluid leak detector	Detects moisture in the centrifuge chamber.
3	Upper strobe (lower strobe is not shown)	Illuminates the interface to allow you to view the interface through the view port.
4	Loading port	Allows access to the filler from the center of the centrifuge.
5	Centrifuge arm	Holds the upper and lower bearing holders.
6	Upper bearing holder	Secures the upper bearing to the tip of the centrifuge arm.
7	Lower bearing holder	Secures the lower bearing at the entrance to the loading port.
8	Filler	Secures the tubing set channel, the connector, and the lines that are attached to the connector to the centrifuge.

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Table 2-5: Functions of the Spectra Optia system centrifuge chamber components (continued)

	Component	Function
9	Gear shroud	Covers the centrifuge gear train.
10	Lights (Not shown. One light is located on the top of the chamber and the second is located on the bottom behind the gear shroud.)	Component of the AIM system. Illuminate the interface to allow the AIM system to view the interface.

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Filler

The filler secures the tubing set channel, the connector, and the lines that are attached to the connector to the centrifuge.The locations of the filler components are shown in Figure 2-4, and the functions are described in Table 2-6.

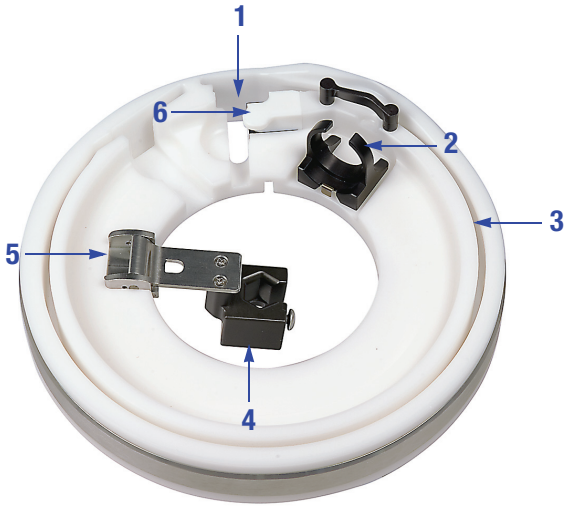

Figure 2-4: Filler components

Table 2-6: Functions of the Spectra Optia system filler components

	Component	Function
1	Aperture plate (arrow points toward the plate)	Plastic component attached to the underside of the filler directly beneath the opening for the connector. The aperture plate ensures uniform lighting to the appropriate areas of the connector, and helps the AIM system control the concentration of cells that flow through the collect port during a collection procedure.
2	Chamber bracket	Secures the chamber of the Collection Set.
3	Groove	Secures the channel and the connector in the filler.
4	Centrifuge collar holder	Secures the lower collar of the tubing set at the opening to the centrifuge loading port.
5	Filler latch	Locks the filler onto the centrifuge.
6	Optical reference	Provides a reference point for the AIM system to use to determine the position of the interface during a procedure.

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Operating Modes

The Spectra Optia system has two modes of operation, Automatic and Semi-Automatic. This section describes the modes.

Automatic Mode

During Automatic mode, the system uses the settings selected for the configuration parameters and the procedure data entered to set and control the pump flow rates, centrifuge speed, packing factor, run targets, and to establish the interface position. The system then uses feedback it receives from the AIM system to control the interface position, so it can remove or collect the desired blood component, and return the fluid remaining in the channel to the patient.

Semi-Automatic Mode

During Semi-Automatic mode, the system does not control the position of the interface. There are two reasons to enter Semi-Automatic mode: You may be required to enter Semi-Automatic mode to resume the procedure if certain alarms occur, or you may choose to enter Semi-Automatic mode under certain procedure conditions. Refer to the Spectra Optia Apheresis System procedure guides for procedure-specific instructions on using Semi-Automatic mode.

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Procedure States

Table 2-7 describes the Spectra Optia system's procedure states. Both Automatic and Semi-Automatic mode include these states.

Table 2-7: Procedure states

State	Description
Load	Operator selects the procedure and loads the appropriate tubing set.
Tubing set test	System verifies that the correct tubing set is properly loaded, and confirms the function of the pumps, valves, and sensors.
Prime	System primes the tubing set to remove air from the set, to perform volumetric tests, and to balance the pumps prior to the start of the run.
Run	Patient is connected and the system performs apheresis, according to the selected procedure.
Rinseback	System returns the blood remaining in the tubing set to the patient after the run is complete to reduce the patient's RBC loss. The operator may choose to perform or skip rinseback.
Disconnect test	System verifies that the lines to the patient are clamped.
Unload	System raises the cassette and unloads the tubing from the pumps.
Procedure summary	System displays the final procedure values.
Next procedure	System prepares for the next procedure.

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Caution Status

Caution status alerts you that the system is operating outside of certain established limits. When the system is operating in Caution status, a yellow border appears on the bottom of the screen. The yellow border disappears if the system operation changes and Caution status no longer applies. To view why the system is operating in Caution status, touch the **Operation Status** tab. The reason is explained in yellow text on the screen.

The system automatically enters Caution status if the AC infusion rate entered is greater than 1.2 mL/min/L of TBV. Refer to the Spectra Optia Apheresis System procedure guides for additional procedure-specific conditions when Caution status applies.

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Spectra Optia System Touch Screen

Navigating the Screen

The Spectra Optia system's touch screen allows you to perform, adjust, and monitor procedures. The screen is divided into several sections, as shown in Figure 2-5 and described in Table 2-8.

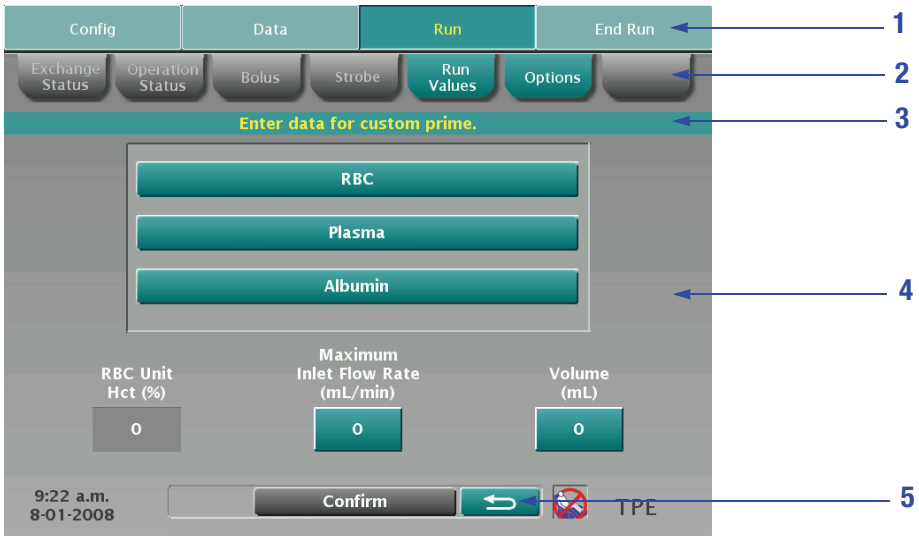

Figure 2-5: Example of a Spectra Optia system screen

Table 2-8: Sections of the Spectra Optia system screen

	Section	Description
1	Menu bar	Contains menu buttons that you touch to show or hide menu tabs.
2	Menu tabs	Appear according to the menu button that you touch. Tabs provide access to screens that allow you to view information or modify the procedure.
3	Message bar	Displays instructions to enter data or information about the status of the procedure.
4	Activity area	Displays tasks to complete and buttons that allow you to: • Navigate to another screen. • Change the operating mode. • Change values or information about the procedure.
5	Action bar	Contains buttons that you touch to perform the action stated on the button or to navigate to a different screen.

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Screen Colors

The Spectra Optia system uses a color scheme to indicate the different procedure states, allowing you to quickly determine the progress of the procedure. Table 2-9 describes the color scheme that corresponds to each procedure state.

Table 2-9: Color schemes for procedure states and conditions

Procedure State	Color
Load, prepare procedure, tubing set test, prime (patient is not connected)	
Run, rinseback, disconnect test (patient is connected)	
Unload, procedure summary, next procedure (patient is disconnected)	

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Screen Buttons

The screen displays active and inactive buttons, as shown in the following examples:

- Active button:

  Active buttons are colored according to the procedure state and appear raised. Touch an active button to enter, change, or save data, or to proceed to the next activity or action.

- Inactive button:

  Inactive buttons are gray. They indicate that the action or the information is not available.

Graphics of buttons and icons

The buttons and icons described in Table 2-10 appear on the monitor or the screens, and either allow you to operate and adjust the Spectra Optia system during an apheresis procedure, or communicate important information. Refer to the Spectra Optia Apheresis System procedure guides for buttons and icons that appear only during specific procedures.

Table **2-10:** Spectra Optia system buttons and icons

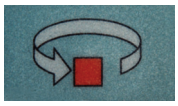
Graphic	Description	Location	Function
	Go back button	• Bottom right side of screens • Top left side of the report summary screen and the report detail screen	Returns you to a previous screen or to the main run screen. The button is available only when it is safe to return to a previous screen. On some screens you must confirm any data you change before you touch the go back button or the data will not be saved.
	Mute button	Bottom left side of screens during an alarm condition	Allows you to mute the sound during an alarm condition. The sound is restored if another alarm occurs.
	Stop button	Bottom left corner of the monitor	Stops the centrifuge and the pumps.

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Table **2-10:** Spectra Optia system buttons and icons (continued)

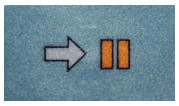
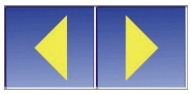
Graphic	Description	Location	Function
	Pause button	Bottom right corner of the monitor	Pauses the pumps.
	Active alarm button	Bottom left side of the screen during an alarm condition	Indicates an active alarm. Takes you to an active alarm screen, or to a list of active alarms if more than one is active.
	Clock button	• Run time graph on the main run screen • Exchange procedures: Run time graph on the exchange status screen	Allows you to view clock time or elapsed time for the run.
	Up/down scroll buttons	• Active alarm screens • Alarm history screen • Procedure selection screen	Allows you to view additional information on the screen.
	Left/right arrow buttons	Strobe screen	• Allows you to adjust the timing of the strobe. • Allows you to view different areas of the channel.
	Left/right scroll buttons	• Alarm action screens • Report summary screen • Report detail screen	• Allows you to scroll through alarm action screens, so you do not have to return to the active alarm screen to view additional causes and actions. • Allows you to scroll through pages of the report summary screen and the report detail screen.
	Check mark icon	• Prepare procedure screen • Patient data screen	Appears on buttons. Indicates the required task is complete or the selection is confirmed.

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Table **2-10:** Spectra Optia system buttons and icons (continued)

Graphic	Description	Location	Function
	Do not connect patient icon	Bottom right side of screens before the patient is connected	Safety feature that reminds you that the patient should not be connected during the current operating state.
	Operator override icon	TBV (total blood volume) button on the patient data screen	Indicates the operator entered the patient's TBV instead of using the volume the system calculated.
	Semi-Automatic mode icon	Bottom right side of run screens	Indicates the system is operating in Semi-Automatic mode.

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3

Installing and Transporting the Spectra Optia System

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Installing the Spectra Optia System

Installation information is included in the shipping container of each Spectra Optia system. An authorized service representative uses this information to install the system in your facility. The service representative also tests the system to confirm it is functioning properly before you begin using it.

Setting Up the Spectra Optia System

Perform the following steps to set up the Spectra Optia system:

1. Carefully unpack the system from the shipping container.
2. Put the system in the desired location and press the wheel pedal to the right side to lock the system in place.
3. Establish a safety boundary of at least 30 centimeters (11.8 inches) around the perimeter of the system from all points within which hazardous material is not permitted. When the centrifuge is spinning, limit access inside the boundary to necessary individuals.
4. Raise the monitor until it is fully upright.
5. Raise the IV pole.
6. Plug in the system to a properly installed, three-wire, grounded electrical receptacle that is protected by an approved branch circuit overcurrent protection/disconnection device. The branch circuit protection/disconnection device must be located away from but close enough to the system so that the system can be easily disconnected from the main power supply if the centrifuge malfunctions.

Turning the Spectra Optia System On and Off

1. Confirm that the proper power cord is attached to the system and plugged into an appropriate electrical receptacle.
2. Press the power switch on the upper-right side of the system to the ON position. The system performs a series of self-diagnostic tests to validate the functionality of the hardware and software before you begin the procedure. Once the tests are complete, the buttons on the screen are enabled and you may begin the procedure.
3. To turn off the system, press the power switch to the OFF position.

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Transporting the Spectra Optia System

Preparing the Spectra Optia System for Transport

1 Unplug the Spectra Optia system and secure the power cord in the power cord holder.

2 Press the IV pole release button located on the left side of the front panel and lower the IV pole.

3 Lower the monitor and lay it over the front panel (Figure 3-1).

Figure 3-1: Lowering the monitor over the front panel

4 Remove the sealer head of the Seal Safe system from the holder and detach the cable from the side of the Spectra Optia system. Separately transport the sealer head and cable to avoid damage to the connection.

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5 Press the wheel pedal to the appropriate position:

- To lock the front wheels in a forward position for moving in corridors, press the wheel pedal to the left.
- To allow free movement of all wheels, press the wheel pedal to the horizontal position.
- To lock the front wheels in position when performing a procedure, press the wheel pedal to the right (Figure 3-2).

Figure 3-2: Front wheels in the locked position

Transporting the System in a Vehicle

To safely transport the system in a vehicle, perform the following steps:

1 Perform steps 1 through 4 of “Preparing the Spectra Optia System for Transport” on page 37.

2 To transport the system in a horizontal position, perform steps a. and b. below. To transport the system in a vertical position, go to step 3.

a. Tip the system backward so that the front wheels are off the ground.

b. Lay the system so that it rests on the rear wheels and the two small wheels on the handle of the system.

3 Carefully load the system into the vehicle. Do not place any weight or objects on the monitor while it is in the transport position.

4 Properly secure the system in the vehicle, so that it remains stable during transport. If you are transporting the system in a vertical position, ensure that you lock the wheels.

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Storing the Spectra Optia System

Cover the Spectra Optia system and store it in a clean environment, according to the specifications stated in Table 9-2 on page 92.

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Configuration and Procedure Data Management

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Configuring the Spectra Optia System

The Spectra Optia system allows you to configure procedure-independent and procedure-specific operating parameters to meet your facility's requirements. Configuration settings for the procedure-independent parameters apply to all procedures. Configuration settings for procedure-specific parameters apply to only the specified procedure type. Several parameters have a default setting. The system uses the default setting unless you enter a different setting. You must touch **Confirm** after you finish configuring the parameters in order for the settings to take effect.

To configure the parameters, perform the following steps:

1. Touch the **Config** menu button. The configuration tabs appear.
2. Touch the tab for the parameters that you want to configure. The corresponding configuration screen appears.
3. Touch the button for the parameter that you want to configure:
   - For parameters with only two settings, toggle between the settings until the setting that you prefer appears on the button.
   - For parameters with more than two settings, a list appears to enable you to select a setting.
   - For parameters that require a numeric setting, a data entry pad appears to enable you to enter a number. The range of acceptable values appears on the data entry pad.
4. Repeat step 3 until you finish configuring the parameters.
5. Touch **Confirm**.

Configuring Procedure-Independent Operating Parameters

You may configure most procedure-independent operating parameters after you turn on the system and before you connect the patient. You may not change the language setting after you select a procedure, however. Tables 4-1 and 4-2 show the configuration parameters and setting options for the procedure-independent parameters.

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System

Table 4-1: System configuration parameters and setting options

Parameter	Description	Setting Options
Language	Language that appears on the screen. You must select a language before you can select a procedure.	• English • Additional languages are available based on the country in which the system is used.
Height units	Unit of measure for the patient's height	• ft in (feet, inches) • cm (centimeters)
Weight units	Unit of measure for the patient's weight	• lb (pounds) • kg (kilograms)
Alarm volume	Volume of the alarm tone	• Low • High
Software	Software version and verification value for each type of procedure. This information is used to confirm that the system software version and verification value for a particular procedure type have not changed after software for a new procedure type was installed.	Not configurable
Decimal	Punctuation used to represent a decimal point	• 0,00 (comma) • 0.00 (point)
Time format	Format used to display the time	• hh:mm (24-hour) • hh:mm (12-hour, am/pm)
Current time	Current time	• hh:mm (24-hour) • hh:mm (12-hour, am/pm)
Date format	Format used to display the date	• mm-dd-yyyy • dd-mm-yyyy
Current date	Current date	• mm-dd-yyyy • dd-mm-yyyy

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Report

Table 4-2: Report configuration parameters and setting options

Parameter	Description	Setting Options
Device	Device that is used to deliver a copy of the report. If you select “Printer”, you must also select a paper size.	• No Device • Printer • Computer
Connection	Test used to verify that a device for printing a report is connected to the system. If the system can verify the connection, “Passed” appears on the button. If the system cannot verify the connection, “Failed” appears.	Test
Paper	Size of paper that is used to print the report, if “Printer” is the device selected.	• Letter • A4
Report	Type of procedure report that you want to view or print.	• Summary (single page report including system serial number, date of procedure, patient information, fluid balance, and initial and final run values) • Detail (Summary report plus additional procedure details, which are reported according to the report update interval you entered.)
IP address	IP address for the device that is used to print the report.	Device-specific. The format for the address is XXX.XX.XXX.XXX. The first five digits must be 172.21 to match the system’s address.
Report update interval (min)	Interval at which procedure information appears on the report.	10 to 60
Port	Port number for the device that is used to print the report.	Format for the number is XXXX. The default number is 9100. It is recommended that you use the default.

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Configuring Procedure-Specific Operating Parameters

You may configure procedure-specific operating parameters before you enter and confirm the patient data. See the appropriate Spectra Optia Apheresis System procedure guide for instructions on configuring procedure-specific operating parameters

Entering Data During the Procedure

The system requires that you enter specific data, such as patient data, during the procedure. You may also change numerical values for operating parameters as you monitor the run. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad also displays the established range for the parameter, or the calculated range if the range adjusts based on related data. See the appropriate Spectra Optia Apheresis System procedure guide for data entry ranges.

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Printing Procedure Data Reports

The Spectra Optia system stores procedure data reports for up to one hundred procedures. Perform the steps below to connect a printer or a computer to the Spectra Optia system, and print a copy of a report.

Connecting a Printer to the Spectra Optia System

Ensure the printer meets the following requirements before connecting it to the system:

- Printer must be network compatible. The system cannot communicate with Universal Serial Bus (USB) or parallel printers.
- Printer must be compatible with PostScript® 3™ page description language. The system does not communicate properly with printers that are only compatible with earlier versions of the language.
- Printer must have a configurable Internet Protocol (IP) address.
- Printer must be able to use port number 9100 for Local Area Network (LAN) printing.
- Ethernet cable used to connect the printer to the system must be a cross-over cable.

Note: If you are connecting the system to the printer via a network device, such as a router or a switch, use a standard Ethernet cable.

Perform the following steps to connect your Spectra Optia system to a printer:

1. Connect one end of the cross-over cable to the printer, and the other end of the cable to the Ethernet port on the Spectra Optia system. The Ethernet port is located on the bottom right side of the back of the system next to the connection for the power cord.
2. Configure the parameters and options on the report configuration screen to use a printer to print a copy of the report (see Table 4-2 on page 44).
3. Touch **Test** on the connection button to verify the connection between the system and the printer.

For additional information about connecting a printer to the Spectra Optia system, visit www.terumobct.com or contact your local Terumo BCT service representative.

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Connecting a Computer to the System

Ensure the computer meets the following requirements before connecting it to the system:

- Computer must have the following applications installed:
  - File Transfer Protocol (FTP) server software
  - Software used to create Portable Document Format (PDF) files from PostScript files
- Ethernet cable used to connect the computer to the system must be a cross-over cable.

Note: If you are connecting the system to the printer via a network device, such as a router or a switch, use a standard Ethernet cable.

For additional information about connecting a computer to the Spectra Optia system, visit www.terumobct.com or contact your local Terumo BCT service representative.

Printing a Report

Perform the following steps to deliver the report to either a printer or a computer for printing:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Report** tab. The screen appears with a list of reports in order of the most recent procedure to the least recent procedure. The reports are identified by the procedure date, start time, procedure type, and the patient's TBV. To view additional reports, touch the scroll bar.

   Note: The button on the screen for the report for a procedure that was just completed is labeled **Current**.

3. Touch the button that corresponds to the report you want to print. The report appears on the screen.
4. Touch the button at the top left side of the report to deliver a copy of the report to the device specified on the report configuration screen:
   - If you selected a printer, **Print** appears on the button.
   - If you selected a computer, **Print to File** appears on the button.
   - If you did not select a device and only intend to view the report, **No Device** appears on the button.

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Selecting Procedure Options

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Selecting Procedure Options

This chapter describes the Spectra Optia system's procedure options. Procedure options are optional steps that you may choose to perform during a procedure. You can select the options after you select a procedure type. The options are summarized in Table 5-1.

Table 5-1: Procedure options

Procedure Option	Description
Rinseback	Allows you to specify if the system should perform or skip rinseback at the end of the run. If you perform a custom prime, the system will automatically skip rinseback unless you specify otherwise.
Custom prime	Allows you to fill the tubing set with specified fluid after you prime the set with saline and before you connect the patient. When treating a patient with a low RBC volume or a low blood volume, such as a pediatric patient, this option allows you to perform a custom prime to maintain isovolemia.
Saline rinse	Allows you to rinse the tubing set with saline solution when you are concerned about hypersensitivity reactions associated with residual ethylene oxide in the tubing set, which is a by-product of sterilization. This option is available to select before you connect the patient.
Blood warmer	Allows you to indicate the use of a blood warmer during the procedure, without changing the configuration setting. If the blood warmer is on the return line, you must enter the volume of the blood warmer tubing set, so that the system can adjust the volume of saline required to perform rinseback.

To select the procedure options, do the following:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Options** tab. The options screen appears.
3. Follow the instructions below to select the procedure options.
4. When you are finished selecting the options, touch **Confirm**.
5. Follow the instructions on the screen to continue the procedure.

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Selecting Rinseback

The default selection for rinseback is **Yes**. The system prompts you to perform rinseback at the end of the run.

If you do not want to perform rinseback, touch the button until **No** appears on the button. If you select **No** and decide later to perform rinseback, perform the following steps:

1. When the run targets screen appears, touch the **End Run** menu button.
2. Touch the **Rinseback** tab.
3. Follow the instructions on the screen to proceed with rinseback.

Selecting and Performing a Custom Prime

The system prompts you to enter data for the custom prime after it primes the tubing set and before you connect the patient. Two methods are available for selecting a custom prime:

- Select the custom prime option on the options screen. The custom prime option is available to select before you connect the patient.
- Accept the system's recommendation that you consider performing a custom prime. The system makes the recommendation based on the RBC volume and total blood volume limit specified in configuration, and the patient data that you entered. If you change the patient data and the system determines that a custom prime may no longer be necessary, it will display an alert.

If you perform a custom prime, you need the following supplies:

- Fluid for the custom prime
- Empty bag
- Filter or blood administration set (optional)
- Appropriate connectors to attach the inlet and return lines to the fluid and the empty bag

Selecting the custom prime option

To select the custom prime option, touch the custom prime button until **Yes** appears on the button.

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Accepting a custom prime recommendation

The system displays a screen after you enter the patient data recommending that you consider performing a custom prime. Perform the following steps:

1. Review the patient data and procedure configuration information on the screen, and confirm that it is correct. The screen also shows the percent of the patient's TBV and RBC volume in the tubing set.
2. To accept the recommendation, touch **Yes**. To decline the recommendation, touch **No**.

Entering data for the custom prime

If you select the custom prime option or accept a custom prime recommendation, the system prompts you to enter data for the custom prime. Perform the following steps:

1. Choose one of the following fluid types to use for the custom prime by touching the corresponding button on the screen:
   - RBC
   - Plasma
   - Albumin
2. Enter the fluid data by touching the corresponding buttons on the screen:
   - RBC unit Hct (%)
     - Available if you select RBC as the fluid type.
   - Maximum inlet flow rate (mL/min)
     - If you are using a filter, determine if the filter has a flow rate limit.
   - Volume (mL) of the custom prime fluid
     - Patient will not receive the full benefit of the custom prime if the volume entered is less than 200 mL plus the volume of the blood warmer tubing set, if you are using a blood warmer.
3. Touch **Confirm**.

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Starting the custom prime

1 Perform the steps that appear on the screen:

   a. Connect the inlet line to the container of fluid to use for the custom prime. Connect a filter, if indicated.

   b. Connect the return line to the empty bag.

   c. Unclamp the inlet line and the return line.

2 Touch **Start Custom Prime**. The status of the custom prime appears on the screen.

Note: Monitor the progress of the custom prime. If the actual volume in the container of custom prime fluid is less than the volume you entered on the screen, you may need to stop the custom prime before it is complete to avoid drawing air into the tubing set.

3 When the custom prime is complete, the screen appears instructing you to connect the patient lines.

Ending the custom prime before it is complete

1 Touch **End Custom Prime**. A screen appears on which you must confirm your decision to end the custom prime.

Note: If you end the custom prime before the system has processed 200 mL of volume, a screen appears informing you that the volume processed was not sufficient to complete the custom prime. Follow the instructions on the screen to resume or end the custom prime.

2 Touch **End Custom Prime**, and then touch **Confirm**.

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Extending the custom prime

You may extend the custom prime by increasing the volume entered for the fluid to use for the custom prime. To extend the custom prime, perform the following steps:

1. When the screen appears instructing you to connect the patient lines, touch the go back button. The screen appears that instructs you to prime the inlet and return lines. **Do not** perform the instructions on the screen.
2. Touch **Confirm**. The screen appears that prompts you to enter the fluid data.
   - If you decide not to extend the custom prime when you reach this screen, touch the **Options** tab. The options screen appears. Change the custom prime button to **No**, and touch **Confirm**.
3. Touch the volume button and enter the sum of the original fluid volume plus the volume of the additional fluid.

   For example, if the volume that you first entered for the custom prime was 250 mL and you decide to extend the custom prime by 30 mL, enter 280 mL.
4. Touch **Confirm**.
5. Touch **Start Custom Prime**.

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Selecting and Performing a Saline Rinse

The system prompts you to perform the saline rinse after it primes the tubing set and before you connect the patient. To select and perform a saline rinse, do the following:

1. To select the saline rinse option, touch the saline rinse button until **Yes** appears on the button. Resume the procedure.
2. When the screen appears with the message "Prepare for saline rinse," perform the steps that appear on the screen:
   a. Spike a new bag of saline that contains at least 250 mL, and squeeze the drip chamber to ensure that saline drips into the chamber.
   b. Connect an empty bag to the return line.
3. Touch **Continue**.
4. Perform the steps that appear on the screen:
   a. Wait 15 minutes to allow any residual ethylene oxide in the tubing set to diffuse into the saline.
   b. Open the inlet saline line and the return saline line.
   c. Unclamp the return line and flush the line to the access site with at least 50 mL of saline.
   d. Close the return saline line.
5. Touch **Start Saline Rinse**. The status of the saline rinse appears on the screen.
6. To stop the saline rinse before it is complete, touch **Cancel Saline Rinse**. A screen appears on which you must confirm your decision to cancel the saline rinse. Touch **End Saline Rinse**, and then touch **Confirm**.
7. After the saline rinse is complete, perform the steps that appear on the screen:
   - Close the inlet saline line
   - Clamp the return line.
8. Touch **Continue**. The screen appears instructing you to connect the patient lines.

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Indicating the Use of a Blood Warmer

Follow the instructions below to indicate the use of a blood warmer during the procedure. To connect and prime the blood warmer tubing, follow the instructions on the screens and in the Spectra Optia Apheresis System procedure guides.

Exchange procedures

1. Select the line on the tubing set to which you want to connect the blood warmer. To use more than one blood warmer, select both the return line and the replace line:
   - To indicate a blood warmer on the return line, touch the return line button until **Yes** appears on the button.
   - To indicate a blood warmer on the replace line, touch the replace line button until **Yes** appears on the button. Ensure you connect the blood warmer to the replace line before you spike the replacement fluid.
2. If you indicated a blood warmer on the return line, enter the volume of the blood warmer tubing set:
   a. Touch the tubing set volume button. A data entry pad appears.
   b. Enter the volume of the tubing set. The volume you entered appears on the button.

Collection procedures

1. Touch the return line button until **Yes** appears on the button.
2. Touch the tubing set volume button. A data entry pad appears.
3. Enter the volume of the blood warmer tubing set. The volume you entered appears on the button.

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6

Loading, Priming, and Removing the Tubing Set

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Loading the Tubing Set

Follow the instructions below to unpack the tubing set, load the set on the system, and test the set before you start the prime. These instructions apply to both the Exchange Set and the Collection Set.

Caution: **You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.**

Note: You must select the type of procedure that you want to perform before you load the tubing set. The system tests the tubing set to ensure that you are using the correct set for the procedure selected.

1. Verify that the tubing set has not expired by checking the expiration date on the cover of the package.
2. Touch **Prepare Tubing Set**. The screen appears instructing you to prepare the set.

Unpacking the Lines and Bags

Put the tubing set package on top of the centrifuge cover with the package label upright and facing you, and remove the cover from the package. Follow the instructions below according to the type of tubing set you are using.

Exchange Set

1. Take out the spike holder. The spike holder holds the replace line (white spikes), the AC line (orange spike), the saline line (green spike), and the extra remove line (yellow clamp). The remove bag with attached remove line is located inside the spike holder.
2. Take out the remove bag and the extra remove line, and put them on the right side of the centrifuge cover.
3. Take out the vent bag and hang the bag on the left side of the IV pole.
4. Remove the replace line and clamp one of the lines to the spikes. Put the line on top of the remove bag.
5. Take out the AC line (orange spike) and the saline line (green spike) and hang the lines over the left side of the system.
6. Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).

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7 Take out the cassette and the channel, and put them on top of the centrifuge cover.

8 Discard the empty tubing set package, according to your standard operating procedures.

Collection Set

1 Take out the product bags and the vent bag and put them on the right side of the centrifuge cover.

2 Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).

3 Take out the AC line (orange spike) and the saline line (green spike) and hang the lines over the left side of the system.

4 Take out the cassette and the channel, and put them on top of the centrifuge cover.

5 Discard the empty tubing set package, according to your standard operating procedures.

Loading the Cassette Into the Cassette Tray

1 Put the bottom of the cassette in the bottom edge of the tray (Figure 6-1).

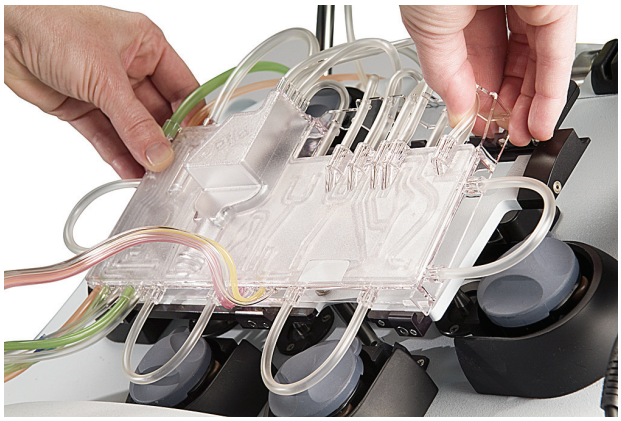

Figure 6-1: Putting the cassette in the bottom edge of the tray

2 Ensure that there is nothing lodged behind the cassette or the tray that could interfere with the loading.

3 Press the top corners of the cassette to snap the cassette into the tray.

4 Hang the bags on the IV pole:

- If you are using an Exchange Set, hang the remove bag on the IV pole.
- If you are using a Collection Set, hang the bags from left to right on the IV pole in this order: Vent bag, Plasma bag, collection bag.

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Loading the Channel in the Centrifuge

1. Open the centrifuge door.
2. Locate the pin on the filler latch. Raise the latch by pushing the pin toward the center of the filler while pulling up the latch.
3. Turn the centrifuge so that the loading port faces you.
4. Fold the channel in half. If you are using a Collection Set, tuck the chamber inside the folded channel.
5. Push the channel up through the loading port and the opening in the center of the filler (Figure 6-2). Lower the filler latch and lock it in place.

Figure 6-2: Pushing the channel through the loading port (Collection Set shown here)

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6 Position the lower collar in the filler latch so that the pink line is not obstructed by the other lines (Figure 6-3).

7 Push the collar into the collar holder until you hear the "click" of the locking pin as it pops out and locks the collar in place. Ensure that the notch at the base of the locking pin is visible. If the collar is locked, you can see the notch (Figure 6-3).

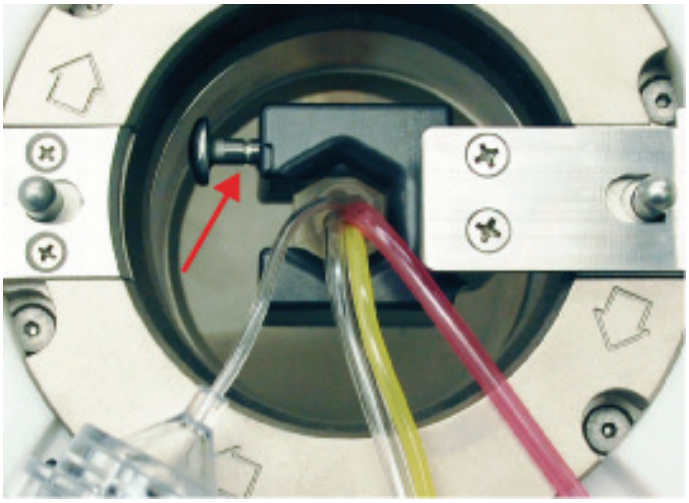

Figure 6-3: Lower collar correctly positioned and locked with the notch visible (Collection Set shown here)

8 Starting with the connector, insert the channel into the groove in the filler, finishing with the inlet port (Figure 6-4). Run your finger over the groove and push down any section of the channel that is not completely inserted in the groove. The channel must sit flush with the groove.

Figure 6-4: Pressing the channel into the groove (Exchange Set shown here)

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9 If you are using a Collection Set, put the chamber into the chamber bracket. Ensure that the chamber sits behind the clip at the opening of the bracket, so that the clip retains the chamber in the bracket. Put the collect line to the chamber behind the lip of the optical reference, so that the line does not block the optical reference (Figure 6-5).

Figure 6-5: Correct position of the collect line to the chamber of the Collection Set

Loading the Lower and Upper Bearings, and the Upper Collar

1 Insert the narrow part of the lower bearing into the lower bearing holder, and the narrow part of the upper bearing into the upper bearing holder (Figure 6-6). Ensure that the braided section of the loop is not twisted.

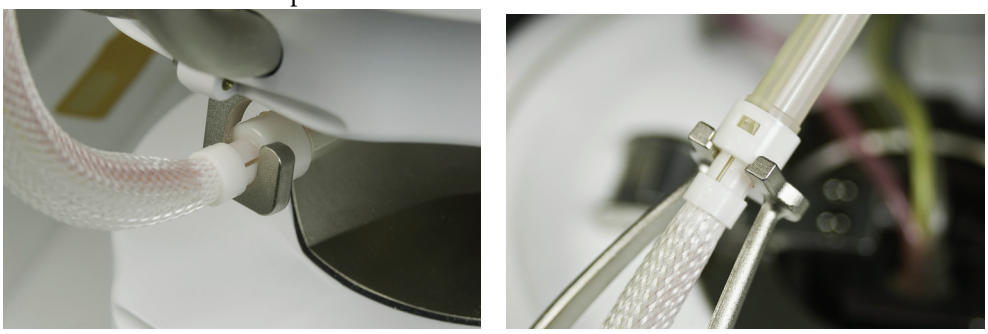

Figure 6-6: Lower bearing inserted in the lower bearing holder (left) and the upper bearing inserted in the upper bearing holder (right)

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2 Position the upper collar below the upper collar holder and insert the line into the holder. Pull the line up to secure the upper collar in the holder (Figure 6-7).

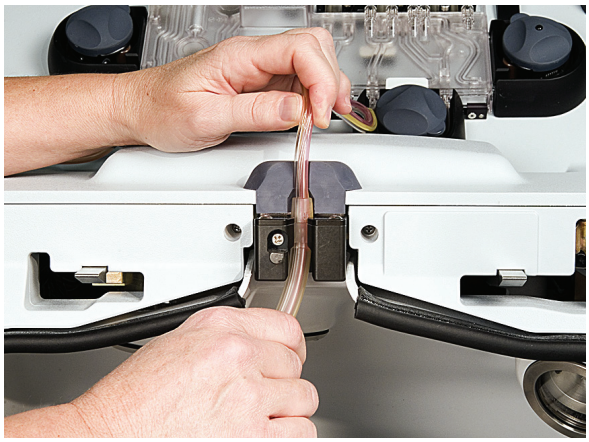

Figure 6-7: Inserting the upper collar into the holder

3 Spin the centrifuge clockwise to ensure that it rotates freely.

4 Close the centrifuge door.

5 Touch **Load**. The system lowers the cassette.

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Testing the Tubing Set

If you are using an Exchange Set, begin at Step 1. If you are using a Collection Set, begin at Step 2.

1. If you are using an Exchange Set, follow the instructions on the screen to perform the following steps, and then go to Step 3:
   a. Close the inlet saline line and the return saline line.
   b. Clamp the extra remove line.
2. If you are using a Collection Set, follow the instructions on the screen to perform the following steps:
   a. Clamp the line to the diversion bag. Close the inlet saline line and the return saline line.
   b. Clamp the line to the sample bulbs.
3. Touch **Continue**.
4. Follow the instructions on the screens to clamp the inlet line and the return line.
5. Touch **Continue**. The system performs several tests to verify that the tubing set and system components function properly, and that the tubing set is loaded correctly.

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Priming the Tubing Set

This section describes how to prime the tubing set after you load and test the set.

1. Follow the instructions on the screen to perform the following steps:
   a. Spike the fluid containers.
   b. Fill the drip chambers.
   c. Insert the AC line in the AC fluid detector.
2. Touch **Start Prime**. The system primes the AC line.
3. Follow the instructions on the screen to open the inlet saline line and the return saline line.
4. Touch **Continue**. The system primes the return line, the inlet line, the RBC line, and the channel. The system primes the set in about 3 to 4 minutes. When the system finishes the prime it sounds a tone. The patient data screen appears.

   Note: The menu buttons at the top of the screen are active so that you may enter or change patient or procedure data during the prime.

5. Follow the instructions on the screen and in the appropriate Spectra Optia Apheresis System procedure guide to continue the procedure.

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Removing the Tubing Set

Once you finish the procedure and raise the cassette, perform the following steps to remove the tubing set:

1. Open the centrifuge door.
2. Remove the upper collar from the collar holder by grasping the lines above and below the collar, and pulling the lines downward.
3. Remove the upper and lower bearings from the bearing holders.
4. If you are using a Collection Set, remove the chamber from the bracket.
5. Gently pull the channel from the filler.
6. Push in the locking pin on the centrifuge collar holder and remove the collar from the holder by grasping the tubes above the collar and pulling upward.
7. Push the filler latch pin toward the center of the centrifuge, and raise the filler latch.
8. Fold the channel in half, and pull the channel through the loading port and out of the centrifuge chamber.
9. Lower the filler latch.
10. Close the centrifuge door.
11. Remove the lines from the fluid detectors.
12. Remove any bags from the IV pole.
13. Press the latch on the upper right corner of the cassette tray, and lift the cassette from the tray.
14. Discard the tubing set, according to your standard operating procedures.

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7

Troubleshooting

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Troubleshooting Alarms

The Spectra Optia system has independent control and safety systems that constantly monitor the performance of the system. If either system detects an operation error or a potentially unsafe operating condition, the system sounds an alarm and illuminates the warning lights on the front panel. The warning lights flash if the safety system detected the error. The system displays information about the alarm and troubleshooting instructions on the screen. Figure 7-1 shows an example of an active alarm screen, which appears if an alarm occurs. Figure 7-2 shows an example of an alarm action screen, which shows the steps to perform to resolve the condition causing the alarm. Tables 7-1 and 7-2 contain descriptions of the different sections of the screens.

The operator plays an essential role in the safe operation of the system. If an alarm occurs, it is crucial for the operator to consider all possible causes for the alarm and thoroughly read the instructions that appear on the screens to resolve the alarm. It is the operator's responsibility to determine if it is safe to continue the procedure, and to follow the appropriate instructions.

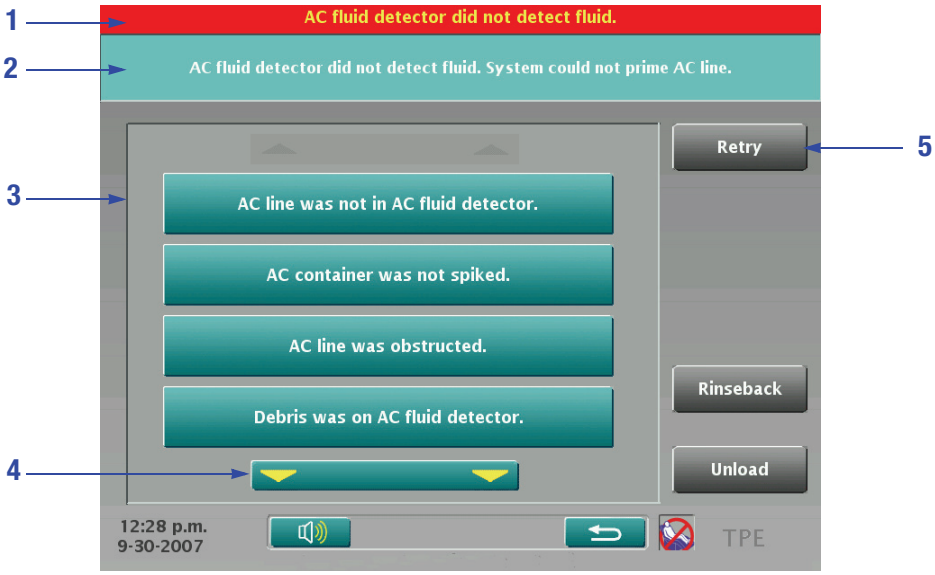

Figure 7-1: Example of an active alarm screen

Table 7-1: Descriptions of the sections on an active alarm screen

	Section	Description
1	Alarm name	States the name of the alarm that occurred.
2	Alarm explanation	Provides a brief explanation of the condition that caused the alarm.

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Table 7-1: Descriptions of the sections on an active alarm screen (continued)

	Section	Description
3	Possible causes	Lists the possible causes of the alarm in order of most likely (top) to least likely (bottom). Each possible cause is an active button that you can touch to display the action steps you should perform to resolve the condition causing the alarm.
4	Scroll button	Indicates that additional possible causes for the alarm condition exist. Touch the button to view the additional causes.
5	Action buttons	Displays buttons of available actions that you can touch to help resolve the condition. For details, read the action steps for the possible cause before you touch an action button.

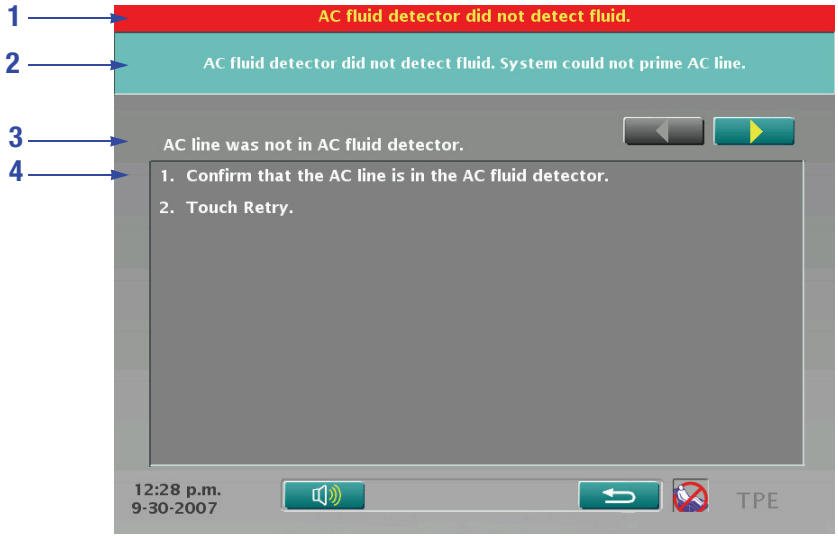

Figure 7-2: Example of an alarm action screen

Table 7-2: Descriptions of the sections on an alarm action screen

	Section	Description
1	Alarm name	States the name of the alarm that occurred.
2	Alarm explanation	Provides a brief explanation of the condition that caused the alarm.

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Table 7-2: Descriptions of the sections on an alarm action screen (continued)

	Section	Description
3	Possible cause	Shows the possible cause of the alarm, which was selected from the list on an active alarm screen.
4	Action steps	Shows the action steps to perform to resolve the condition causing the alarm.

If an alarm occurs, perform the following steps:

Note: If you want to silence the alarm sound, touch the mute button at the bottom of the screen.

1. Read the alarm name and the alarm explanation.
2. Read the list of possible causes for the alarm, and identify the most probable cause for the alarm.
3. Touch the button for the cause that you identified. The alarm action screen appears.
4. Follow the steps on the screen to resolve the condition causing the alarm.
5. If the actions for the cause you identified do not resolve the condition, repeat steps 2 through 4 until you resolve the condition. To view previous or subsequent alarm action screens, touch the scroll buttons. To return to the active alarm screen, touch the go back button.
6. If you are instructed to contact your service representative for assistance, write down the name of the alarm exactly how it appears on the screen. Be prepared to provide the name to your service representative.

Troubleshooting Multiple Alarms

To view a list of active alarms, do the following:

1. Touch the active alarm button at the bottom of the screen. The screen of active alarms appears with a list of active alarms.
2. Touch the button of the alarm that you want to troubleshoot.
3. To exit the screen, touch the go back button.

Note: You must resolve all conditions causing alarms before you can resume the procedure. The active alarm button appears at the bottom of the screen if there are additional conditions to resolve. Some conditions may resolve themselves when you troubleshoot other conditions, and as a result will disappear from the list of active alarms.

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Viewing Alarm History

1 Touch the **Data** menu button. The menu tabs appear.

2 Touch the **Alarm History** tab. The alarm history screen appears with a list of alarms that have occurred, including the time the alarm occurred.

3 To exit the screen, touch the go back button.

Muting the Alarm Sound

You may silence the alarm sound for 2 minutes by touching the mute button on the lower left corner of the screen. The system sounds a reminder tone every minute thereafter to remind you that there is an active alarm. If a new alarm occurs, the system restores the alarm sound.

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Managing Anticoagulation of the Extracorporeal Circuit

Caution: Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit.

Proper anticoagulation of the system's extracorporeal circuit ensures that the flow of blood and fluid through the circuit is not obstructed during the procedure. Terumo BCT recommends that you use an inlet:AC ratio up to 15:1 when using ACD-A. The system's default inlet:AC ratio depends on the procedure selected. Refer to the Spectra Optia Apheresis System procedure guides for the default ratios. You may need to use a different ratio, however, for a patient with a unique hematologic condition. If the circuit is not adequately anticoagulated, Platelet aggregates or clots may form, and eventually cause an obstruction in one or more of the following areas:

- Filter at the bottom of the reservoir
- Remove line (Exchange Set)
- Collect line or Plasma line (Collection Set)
- Lines in the centrifuge, which can result in an unstable interface

To eliminate the aggregates or clots, decrease the inlet:AC ratio. If an alarm occurs indicating a possible obstruction, follow the instructions on the alarm action screen, and monitor the system for the rest of the procedure. If you do not eliminate the obstruction, the system may require that you discontinue the procedure.

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Handling Fluid Leaks

The fluid leak detector is a strip of moisture-sensitive material running down the back wall and floor of the centrifuge chamber. If it detects moisture inside the centrifuge chamber, or if it is not functioning correctly, an alarm occurs.

1. If you do not see signs of blood or moisture, clean the fluid leak detector with an alcohol pad using a gentle side-to-side motion. Then dry the detector with a clean cloth or gauze pad.

   Note: Refer to "Disinfecting the System" on page 87 for instructions on disinfecting the Spectra Optia system after leaks or spills.

2. If you see a fine spray of blood or moisture on the inside walls of the centrifuge chamber, a small leak exists. Do one of the following to discontinue the procedure:
   - If the patient is not connected and the cassette is lowered, touch **Unload** and unload the tubing set.
   - If the patient is connected and the procedure is in progress, touch **Rinseback**.
   - If rinseback is not an option, touch **Disconnect**.
3. If you see a pool of blood in the centrifuge chamber, touch **Disconnect** and disconnect the patient.

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Resuming a Procedure After a System Reset

The system resets itself under the following conditions:

- Power to the system fails and is then restored.
- You touch **Reset**, according to instructions on an alarm screen.
- An alarm condition causes the system to reset itself.
- You turn the system off and then on again.

After the reset, the system performs a series of tests to ensure that it is safe to resume the procedure. A screen appears with instructions for how to proceed after the reset. Do the following:

1 Follow the instructions on the screen to resume the procedure at the point before the reset occurred. You may also choose to discontinue the procedure.

- If the reset occurred during a run and you chose to continue the procedure, a screen appears asking you to ensure that both saline lines are closed. Follow the instructions on the screen to confirm that the lines are closed.
- If an alarm was active when the reset occurred, the action buttons that appear on the screen will be the same as the buttons that were available on the alarm screen. If the alarm condition still exists after you complete the instructions on the screen, the alarm will recur.

2 Verify that the system restored the patient and procedure data you entered before the reset occurred. The system restores the data only if the tubing set cassette was in the lowered position when the reset occurred.

- If the reset occurred before you started a custom prime, the system does not restore the custom prime data. Go to the screen that instructs you to enter the custom prime data and re-enter the data.

3 Verify that you completed the task that appeared on the screen before the reset occurred. Depending on when the reset occurred, you may need to repeat a sequence of steps.

- If the reset occurred during administration of a fluid bolus, the system discontinued the bolus. Go to the exchange status screen to view the volume that the system administered.

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Performing a Manual Rinseback

Important: You should read and understand these instructions before you attempt to perform a manual rinseback.

If you are not able to complete a procedure due to an alarm condition, a power interruption, or a system malfunction, you may choose to perform a manual rinseback. Perform the following steps to complete a manual rinseback.

Sealing and clamping the lines

1. Clamp the inlet and return lines.
2. Close the saline lines.
3. Disconnect the inlet line from the patient.
4. Seal the AC line.
5. If you are using an Exchange Set, seal the remove line and the replace line.
6. If you are using a Collection Set, seal the collect line and the Plasma line.

Note: Ensure that you do not seal the line to the vent bag. If you seal the line, you will not be able to resume the manual rinseback.

7. Turn off the Spectra Optia system.

Draining the channel

1. Open the centrifuge door. If the door does not open, follow the instructions on page 79 to manually open the door.
2. Remove the channel from the filler and hang it on the IV pole with the inlet line at the highest point, so that the fluid in the channel drains into the cassette reservoir.

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3 Ensure that the RBC valve is in the return position (Figure 7-3), or the fluid will not drain.

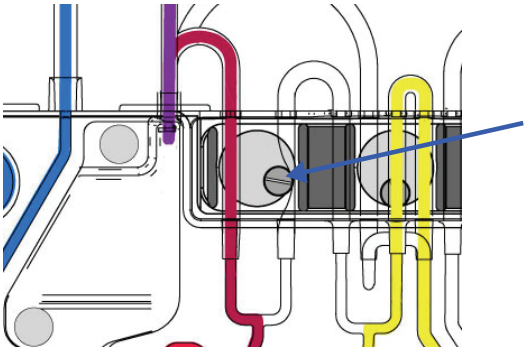

Figure 7-3: RBC valve in the return position (Exchange Set shown here)

Returning the Fluid to the Patient

1 Remove the rotor from the return pump:

a. Push in the rotor and turn it to the left to unlock.

b. Pull the rotor off the pump.

2 Use a hemostat to clamp the RBC line directly below the cassette (Figure 7-4).

Note: Do not seal the RBC line instead of clamping it. If you seal the line, the tubing set could leak when you raise the cassette to unload the set.

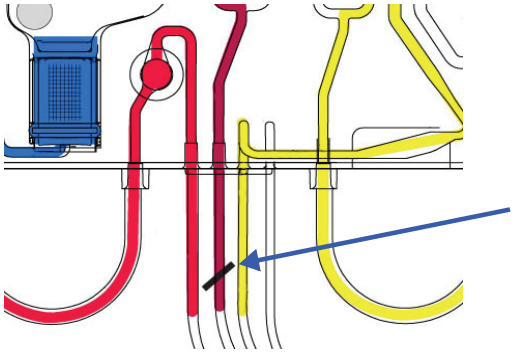

Figure 7-4: Where to clamp the RBC line (Exchange Set shown here)

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3 Unclamp the return line (Figure 7-5).

Figure 7-5: Return line unclamped

4 Gently squeeze the vent bag to push the fluid from the reservoir to the patient. This should take several minutes to complete. Do not try to expedite this process by applying more pressure to the bag.

Warning: Do not apply excess pressure to the vent bag when pushing fluid from the reservoir to the patient during a manual rinseback or you could damage the Red Blood Cells that you are returning to the patient.

5 When the level of fluid in the reservoir drops to the level of the reservoir filter (Figure 7-6), clamp the return line and stop squeezing the vent bag.

Warning: Do not continue to squeeze the vent bag after the fluid in the reservoir reaches the level of the reservoir filter during a manual rinseback. If you continue to squeeze the bag, you could deliver air to the patient.

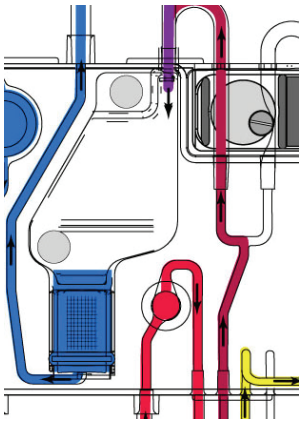

Figure 7-6: Level of fluid in the reservoir at the level of the reservoir filter (Exchange Set shown here)

6 Disconnect the patient.

7 Remove the hemostat from the RBC line. Ensure that you do this before you raise the cassette in step 9, or the return pressure sensor will leak.

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8 Replace the rotor on the return pump:

a. Pull the tubing out of the pump housing and down toward the cassette.

b. While holding the return pump tubing in the position described in step a., push the rotor back in the housing.

9 If the system functions, perform the following steps:

a. Turn on the system.

b. Touch **Disconnect** to discontinue the procedure.

c. Touch **Unload** to raise the cassette.

d. Unload the tubing set.

10 If the system does not function, manually raise the cassette according to the instructions on page 80, and then unload the tubing set.

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Manual Method for Opening the Centrifuge Door and Raising the Cassette

If the power to the system is interrupted when the centrifuge is spinning, or the system does not function correctly, the pumps stop and the centrifuge door may not open. To unload the tubing set, you need to manually open the centrifuge door and raise the cassette.

Manually Opening the Centrifuge Door

1. Confirm that the system is turned off. Unplug the system from the power source.
2. Remove the cap from the centrifuge door lock-release hole, which is located near the top-right corner of the centrifuge door.
3. Insert the centrifuge door key or a long, thin, metal rod into the lock-release hole (Figure 7-7). Push in the key until you hear a click.

Note: Do not use a cotton swab, stick, or other breakable object to manually open the centrifuge door, as it may break and jam the door.

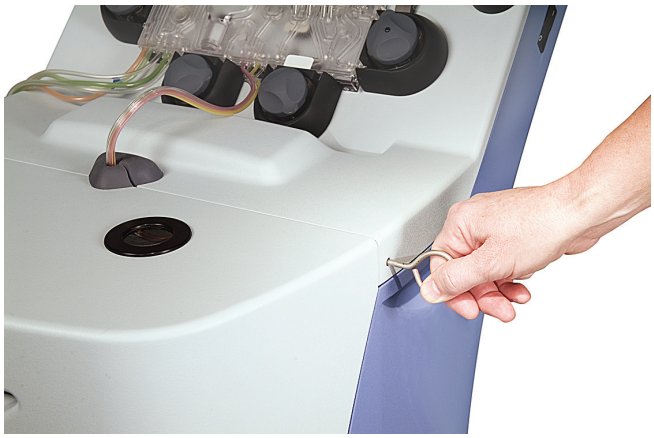

Figure 7-7: Centrifuge door key in the lock-release hole

4. Remove the key.
5. Squeeze the centrifuge door handle and gently lower the door. Replace the cap into the lock-release hole.

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Manually Raising the Cassette

If a system malfunction occurs and you must turn off the Spectra Optia system, you can manually raise the cassette to remove the tubing set. To raise the cassette and open the valves, perform the following steps.:

Warning: Do not touch Unload to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

1. Confirm that the patient is disconnected.
2. Seal or clamp the lines to the fluid containers.
3. Unplug the system from the power source.
4. Turn each valve to the neutral position using a flat-blade screwdriver (Figure 7-8).

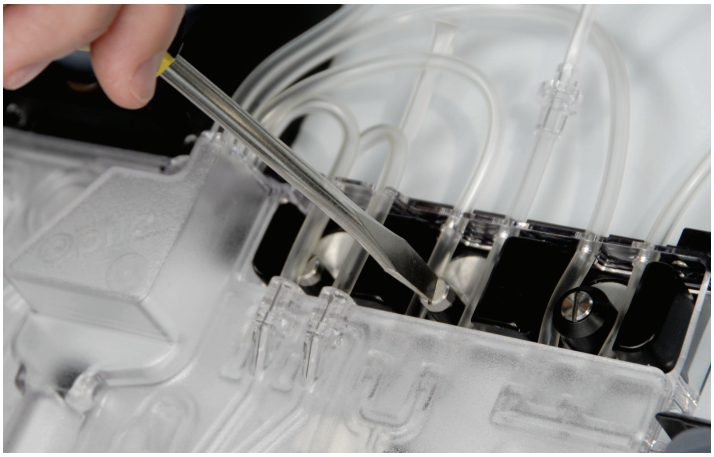

Figure 7-8: Valves turned to the neutral position

5. Remove each pump rotor from the pumps:
   a. Push in the rotor and turn it to the left.
   b. Pull the rotor off the pump.

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6 Insert the screwdriver into the small hole in the vent on the back of the system (Figure 7-9) until you engage the slotted end of the pin attached to the back of the cassette tray. You may need to angle the screwdriver to locate the pin.

Figure 7-9: Screwdriver inserted n the hole in the back of the system

7 Turn the screwdriver counterclockwise until it no longer turns, and the cassette tray is in the fully raised position.

8 Follow the instructions on page 66 to remove the tubing set from the system.

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8

Maintaining the Spectra Optia System

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Cleaning the Spectra Optia System

Clean the Spectra Optia system after every procedure and on a weekly basis. Other than to ensure that the system is clean and undamaged before use, you are not required to perform system maintenance.

Warning: Turn off the system before cleaning to prevent possible electrical shock or damage to the equipment.

Caution: Clean the Spectra Optia system using a mild cleaning solution, or a mild detergent. Industry standard practice defines mild detergent as a solution or detergent that is safe on skin and on washable surfaces, such as hand dishwashing liquid. Use of a solution that is not compatible with the materials on the system may damage the material or operating characteristics of the system.

The information in this section explains the recommended cleaning frequency and cleaning procedures for the Spectra Optia system, including:

- Routine cleaning after every procedure
- Weekly cleaning
- Periodic cleaning

Routine Cleaning After Every Procedure

Warning: When cleaning and disinfecting equipment surfaces that might have been exposed to blood, take adequate precautions to prevent possible exposure to and transmission of infectious diseases.

Clean the surfaces and the touch screen of the Spectra Optia system to remove all traces of dirt and fluid, using a solution of mild detergent and water, and a clean cloth or gauze pad. In case of a blood spill, follow the instructions under “Disinfecting the System.”

Weekly Cleaning

Clean the sensors, the detectors, and the valves on the front panel of the Spectra Optia every week, according to the instructions below.

Cleaning the sensors and the detectors

Fluid spilled on the sensors and the detectors could interfere with the system operation and may not be visible. It is important to clean the sensors and the detectors weekly and after any spill.

Use a gauze pad or cotton swab dampened with water to clean the sensors and detectors. Terumo BCT recommends using distilled water on sensors and detectors. Do not use detergent

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to clean the sensors and detectors because detergent may leave a film residue if it is not thoroughly removed. Dry the RBC detector immediately after cleaning.

Caution: Do not spray or douse the Red Blood Cell (RBC) detector with liquid to clean it. Using an excessive amount of liquid can damage the detector. If you must spray the front panel, cover the RBC detector beforehand.

Cleaning the valves

Clean the surfaces of the valves using a solution of water and mild detergent, and a cotton swab.

Periodic Cleaning

Cleaning the pump housings and pump rotors

Perform the following steps to clean the pump housings and pump rotors:

1. Remove each pump rotor from the housing:
   a. Push in the rotor and turn it to the left (Figure 8-1).
   b. Pull out the rotor from the housing.

Figure 8-1: Removing the rotor from the pump housing

2. Clean the housing and the rotor using a solution of mild detergent and water, and a clean cloth or gauze pad. Allow the surfaces to air dry before you replace the rotor.

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3 Align the rotor with the housing. Ensure that the metal bar in the housing aligns with the corresponding slot in the rotor. Push in the rotor and turn it to the right to lock the rotor in place. If you do not properly install the rotor, an alarm will occur the next time you load a tubing set.

Note: Ensure that you install the rotor with the black dot in the housing for the replace/collect pump.

Cleaning the fluid leak detector

The fluid leak detector is a strip of moisture-sensitive material that runs down the wall and floor of the centrifuge chamber. To clean the detector of dirt or debris, wipe it with an alcohol pad. To clean the detector after a large fluid spill, do the following:

1 Using a clean cloth and a solution of mild detergent and water, wipe the surface along the ridges of the detector using a gentle, side-to-side motion. Be careful not to damage the ridges of the detector. Cleaning with mild detergent and water removes organic material, including oils.

2 Allow the detector to air dry.

3 Wipe the detector with water to remove any residue.

4 Dry the detector with a clean cloth or gauze pad.

Cleaning the glass covers on the lights in the centrifuge chamber

Debris on the glass covers of the lights on the top and bottom of the centrifuge chamber can affect the function of the AIM system. To clean the covers, do the following:

1 Wipe the surfaces of the covers using water and a gauze pad or other lint-free cloth.

2 Allow the covers to air dry.

3 Wipe the covers again with water to remove any residue.

4 Dry the covers with a gauze pad.

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Disinfecting the System

Use a 0.25% sodium hypochlorite (bleach) solution, consisting of 1 part 5.25% to 6.0% commercial household bleach diluted with 18 parts water, to disinfect any portion of the Spectra Optia system that comes in contact with blood. For maximum effectiveness, the solution should be prepared the day it is used.

Caution: **Disinfect the Spectra Optia system using a 0.25% sodium hypochlorite (bleach) solution. Use of a stronger bleach solution may damage or discolor the system.**

Note: The bleach solution may leave streaks on the screen. A mild, non-abrasive detergent or water can be used to remove the streaks.

If a blood spill occurs, check the following areas and disinfect them, according to your facility's standard operating procedures:

- System surface
- Front Panel
- Centrifuge chamber

Disinfecting the Surface of the System

Use a clean cloth, gauze, or cotton swab dampened with freshly prepared bleach solution to disinfect the surface of the Spectra Optia system. Allow the surface to air dry.

Disinfecting the Front Panel

To disinfect the sensors, detectors, valves, pump housings, and pump rotors on the front panel, follow the instructions under "Weekly Cleaning" on page 84, and "Periodic Cleaning" on page 85, substituting the bleach solution for the water or mild detergent.

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Disinfecting the Centrifuge Chamber

A blood spill may occur in the centrifuge chamber. Cleaning a spill inside the centrifuge chamber is the operator's responsibility, unless the blood is in an area that cannot be cleaned without disassembling the machine. In that case, contact your service representative for assistance.

Disinfecting the fluid leak detector and the glass covers on the lights

Follow the instructions under “Cleaning the fluid leak detector” and “Cleaning the glass covers on the lights in the centrifuge chamber” on page 86, substituting the bleach solution for mild detergent and water.

Removing and disinfecting the filler

1. Open the centrifuge door by grasping the handle and pushing upwards with your fingers to release the lock.
2. Push the filler latch pin (Figure 8-2, number 1) toward the center of the centrifuge and raise the filler latch.
3. Push the filler locking pin (number Figure 8-2, number 2) toward the center of the centrifuge. With the pin pushed in, grasp the edge of the filler and lift up to raise the filler off the centrifuge.

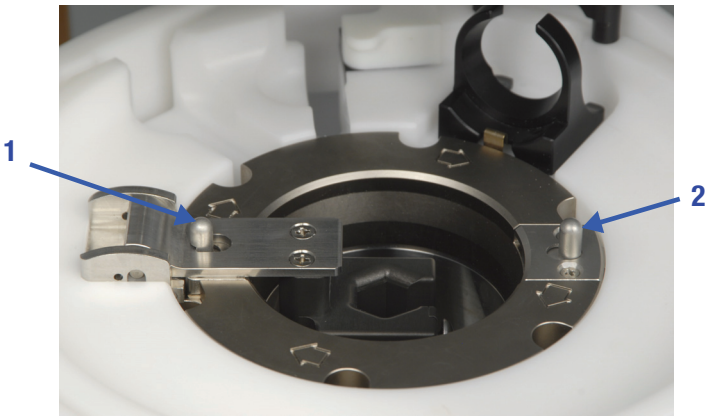

Figure 8-2: Locations of the filler latch pin (1) and the filler locking pin (2)

4. Wipe the filler using bleach solution and a clean cloth or gauze pad. Use a cotton swab to clean the groove of the filler, and a dry swab or alcohol pad to remove excess fluid. Allow the filler to air dry.

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Installing the filler

1 Align the two notches on the bottom of the filler with the two metal pins on the centrifuge (see Figure 8-3), and firmly press the filler down until the filler locking pin is securely in place. You should hear a click when the pin is in the correct position.

Figure 8-3: Aligning the notches on the filler with the pins on the centrifuge to install the filler

2 Verify that the filler is secure by pulling it upwards. If the filler is properly locked, it should remain firmly in place.

3 Lower the filler latch.

4 Close the centrifuge door.

Performing Preventive Maintenance

To prolong equipment life and to ensure maximum performance of the Spectra Optia system, a qualified service technician should calibrate the system and perform preventive maintenance every 6 months, with a compliance window of ±30 days from the scheduled date of the maintenance. Contact your Terumo BCT representative for more information.

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9

Spectra Optia System Specifications

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Spectra Optia System Specifications

General System Specifications

Electrical

Table 9-1: Electrical power and safety

Characteristics	Performance	Conditions
Electrical power requirements	100 to 240 Vac 10 to 4 A 50/60 Hz	Where a circuit breaker provides excess current protection
Ethernet connection	Connector is electrically isolated	• Location where a device can be connected to the system to print reports • Location where service personnel can connect to the system to download procedure information to a computer when a patient is not connected
Safety certifications	Meets the requirements of EN 60601-1 and EN 61010-2-20	CE Marking
	Device is certified by CSA International in accordance with applicable U.S. and Canadian standards. For applicable standards for the product, see Table 9-19 on page 101.	CSA Certification to applicable U.S. and Canadian standards
	Meets the requirements of category IP21 of IEC 60529	

Environmental

Table 9-2: Environmental

Characteristics	Performance	Conditions
Ambient operating temperature	15.5 °C to 27.7 °C (60 °F to 82 °F)	
Ambient operating humidity	8% to 80%	Relative humidity (RH), noncondensing

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Table 9-2: Environmental (continued)

Characteristics	Performance	Conditions
Cleaning	Surface of the device can be cleaned and disinfected; pump rotors can be removed for cleaning; channel leaks are contained within the centrifuge chamber, and chamber can be cleaned and disinfected.	Device is not damaged by cleaning and disinfecting with water, mild detergent, or a 0.25% sodium hypochlorite solution, as described in Chapter 8.
Access by foreign material	Device is protected against access by foreign objects and falling water.	
Restrictions	Device is not for use in an explosive atmosphere.	
Shipping/storage temperature	0 °C to 60 °C (32 °F to 140 °F)	
Shipping/storage humidity	8% to 80%	Relative humidity (RH), non-condensing

Physical

Table 9-3: Physical

Characteristics	Performance	Conditions
Floor space required	0.43 m^2 (4.6 ft^2)	Applies to a floor slope of less than 5°
Minimum clearance	30 cm (11.8 in) around the perimeter of the device	
Height	• 106.4 cm (41.9 in) (without the IV pole) • 162.1 cm (63.8 in) (with the IV pole)	
Width	52.7 cm (20.75 in)	
Depth	81.3 cm (32.0 in)	
Weight	92 kg (202 lb)	

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Sound level

Table 9-4: Operating sound level

Characteristics	Performance	Conditions
Average sound level during the run state	68 dBA to 70 dBA	Normal run conditions

System Components

Centrifuge

Table 9-5: Centrifuge speed and g-force

Characteristics	Performance	Conditions
Maximum centrifuge speed	3000 rpm	
Maximum g-force in the channel	1200 g	Device is operating at the maximum speed.

Pumps

Table 9-6: Pump flow rates

Characteristics	Performance	Conditions
AC pump	Up to 12 mL/min	When a patient is connected
Inlet pump: • Exchange procedures • Collection procedures	 • Up to 142 mL/min • 10 to 125 mL/min	
Plasma pump: • Exchange procedures • Collection procedures	 • Up to 142 mL/min • Up to 125 mL/min	
Collect pump (collection procedures): • During the run • During a chamber flush	 • Up to 150 mL/min • 1 to 15 mL/min	

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Table 9-6: Pump flow rates (continued)

Characteristics	Performance	Conditions
Replace pump (exchange procedures): • During the run • During a bolus	• Up to 150 mL/min • 10 to 120 mL/min	Characteristic of the flow rate range for administration of a bolus represents the range available to the operator.
Return pump: • During the run • During rinseback	• Up to 295 mL/min • 2 to 100 mL/min	Characteristic of the flow rate range for rinseback represents the range available to the operator.
Fluid balance accuracy during exchange procedures	± 8% of commanded balance	Normal operating conditions with no line restrictions. Pump accuracy can be affected by the temperature and viscosity of fluids.
Volume accuracy, all pumps	± 6% of displayed value	Normal operating conditions with no line restrictions. Pump accuracy can be affected by the temperature and viscosity of fluids.

Sensors and Detectors

Table 9-7: Anticoagulant and replacement fluid detectors

Characteristics	Performance	Conditions
Time to alarm	< 2 seconds after sensing the absence of fluid. An alarm is generated when the sensor is unloaded after fluid is present.	

Table 9-8: Centrifuge pressure sensor

Characteristics	Performance	Conditions
Operating range	400 to 2000 mmHg	
Alarm point	1350 mmHg	Accuracy ± 10%

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Table 9-9: Fluid leak detector

Characteristics	Performance	Conditions
Detection sensitivity	Detects fluid leaks when moisture reaches the wall or bottom of the chamber. Capable of detecting a 0.5 mL drop of fluid in the centrifuge.	Normal operating conditions

Table 9-10: Inlet and return pressure sensors

Characteristics	Performance	Conditions
Operating range	-300 to +500 mmHg	
Default alarm point: • Inlet pressure sensor • Return pressure sensor	 • -250 ± 30 mmHg • +400 ± 37 mmHg	
Accuracy	± 6% of the sensor reading or ± 20 mmHg, whichever is greater	

Table 9-11: Red Blood Cell detector

Characteristics	Performance	Conditions
RBC detection level	> 1.5% hematocrit	During a TPE procedure, the system automatically diverts the fluid away from the remove bag when it detects RBC. During an MNC collection procedure, the system initiates a collection phase when it detects RBC exiting the chamber.

Table 9-12: Low-level and high-level reservoir sensors

Characteristics	Performance	Conditions
Pump stroke volume between sensors	49 ± 9 mL. Sensors detect foam as air.	Level sensor requires a load force of > 5 lb (2.3 kg) each (> 10 lb [4.5 kg] total).
Alarm occurrence	When fluid is not detected at the low-level sensor, the sensor stops the pumps before air enters the line.	System performs a duplicate (redundant) safety check.

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Touch screen

Table 9-13: Touch screen

Characteristics	Performance	Conditions
Graphical user interface (GUI) touch screen.	Monitor holds a touch screen that provides tactile operator interface. Includes a speaker for alarms, alarm lights, and two external dedicated buttons with icons (stop button and pause button).	Screen is touched to cause a change in resistance.
Size	26.7 cm (10.5 in) diagonal measurement	
Screen type	Color, liquid crystal screen (LCD). Monitor holds backlight bulbs, which a service representative can replace when necessary.	

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System Software

Safety system

Table 9-14: Safety system

Characteristics	Performance	Conditions
Alarms	Audio alarm (mutable), steady red light, flashing red light, alarm screen	Light flashes if a Safety system alarm occurs; light is steady if a Control system alarm occurs.
Safety	No single-point of failure causes injury to the patient or the operator.	

Alarms

Table 9-15: AC infusion rate alarm

Characteristics	Performance	Conditions
Detection method	AC infusion to patient > limit specified by the operator, averaged over the system filling and emptying the reservoir one time	AC infusion rate is too high.

Table 9-16: AC pump flow rate alarms

Characteristics	Performance	Conditions
Detection method	• AC pump overspeed • AC flowing directly to the patient • Inlet:AC ratio is too low • Inlet:AC ratio is too high	• AC pump speed > 120 rpm. Pump stopped within two revolutions. • AC pump flow rate > inlet pump flow rate for more than 0.4 mL net AC pumped to the patient • System calculated inlet:AC ratio > 20% below the operator-specified value for 2 mL of inlet volume • System calculated inlet:AC ratio > 20% above the operator-specified value for 10 mL of inlet volume
Delay time	< 5 cycles of occlusion	

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Table 9-17: Inlet:AC ratio alarms

Characteristics	Performance	Conditions
Detection method	• AC ratio < 20% below the configured value • AC ratio > 20% above the configured value	• AC ratio is too low. • AC ratio is too high.
Delay time	Alarm occurs when either of the above conditions is met during the run until rinseback begins.	

Tubing Sets

Exchange Set and Collection Set

Table 9-18: Exchange Set and Collection Set

Characteristics	Performance	Conditions
Extracorporeal blood volume (approximate): • Exchange Set • Collection Set	• 185 mL • 191 mL	
Remove bag volume	6 L	Bag is on the Exchange Set only.
Collection bag volume	940 mL	Bag is on the Collection Set only.
Reservoir volume: • Between the high and low level sensors • Entire reservoir	• 49 mL • 56 mL	Reservoir prevents > 0.5 mL of air from entering the return line.
Sterile barrier filters	0.2 microns. Maintain functionally closed system.	Filters are on the saline, AC, and accessory lines of the Collection Set only.
Reservoir filter	Prevents particles (200 microns or larger) from entering the line at the bottom of the reservoir	
Inlet line trap	Traps large particles	
AC check valve	Prevents the free flow of AC through the tubing set	

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Table 9-18: Exchange Set and Collection Set (continued)

Characteristics	Performance	Conditions
RBC residual volume: • Rinseback performed • No rinseback performed	• ± 10 mL • Extracorporeal blood volume of the tubing set multiplied by the patient's Hct	Normal operating conditions
Channel life: • Exchange Set • Collection Set	• 6 hours • 8 hours	Normal operating conditions

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Symbols and Certifications

The symbols shown in Table 9-19 may appear on the Spectra Optia system, as applicable.

Table 9-19: Spectra Optia system symbols and certifications

Symbol	Definition
CE 0086	Indicates that the device is manufactured in conformance with the European Council Directive 93/42/EEC of June 14, 1993, concerning medical devices. This mark with the Notified Body Number 0086 indicates the approval by the British Standards Institute for these devices within the European Community.
C US	Indicates that the device is certified by CSA International in accordance with applicable U.S. and Canadian standards for conformance with the requirements of CAN/CSA-C22.2 No. 601-1-M90, CAN/CSA-C22.2 No. 1010.2.20-94, and UL 60601-1, as well as the applicable respective amendments to these standards.
	Indicates that the device is classified as type BF applied part, according to the safety standard IEC/EN 60601-1. This classification is based on the degree of protection against electrical shock, as defined in the standard.
	Indicates that the user must read the accompanying documents before operating the device to ensure safe operation.
IP21	Indicates that the device is protected against access by solid objects and falling water, as defined in standard IEC 60529.
	Indicates that the device requires an alternating supply current.
	Indicates a protective conductor terminal. Located near the chassis' grounding locations.
	Indicates a protective earth ground. Located near the chassis' grounding locations.

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Table 9-19: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
	Indicates that the main power is turned on.
	Indicates that the main power is turned off.
	Indicates WEEE Directive: Product complies with waste electrical and electronic equipment directive 2002/96/EC (WEEE).
PYRO	Indicates that the product is non-pyrogenic.
2	Not for Reuse: Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.
	Indicates the manufacturer of the product when accompanied by the name of the manufacturer.
	Indicates the date of manufacture (or sterilization date, if the product is sterile) when accompanied by a specific date.
EC REP	Indicates the authorized representative of the manufacturer when accompanied by the name of the representative.

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Table 9-19: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
	Indicates the product quantity when the quantity is placed in the square.
LOT	Indicates the lot of the product when accompanied by a number.
	Indicates the expiration date of the product when accompanied by a specific date.
STERILE EO	Indicates a sterile fluid pathway using ethylene oxide (EtO).
Rx Only	Indicates that the use of product is by prescription only.
REF	Indicates the product catalog number when accompanied by a number.
	Indicates that the user must read the instructions for use before application.
	Indicates that the product must be kept away from sunlight.
	Indicates that the product must be kept dry.

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Table 9-19: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
DER GRÜNE PUNKT	Indicates that the product packaging complies with European Directive 94/62/EC for packaging and packaging waste.
PHT DEHP	Indicates that the product contains phtalates, specifically Di(2-ethylhexyl) phtalate (DEHP).

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10

Seal Safe System

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Seal Safe System Description and Components

Caution: Use the Seal Safe system only on tubing distributed by Terumo BCT. The Seal Safe system may not perform as expected on other tubing.

The Seal Safe system is designed to seal tubing that is distributed by Terumo BCT. The system generates a radio frequency (RF) electromagnetic field between the jaws of the sealer head to seal the tubing. The Seal Safe system consists of the following components:

- Sealer head
- Holder for the sealer head
- RF cable
- RF generator (inside the Spectra Optia system)
- Disposable splash guard (optional)

Installing the Seal Safe System

The Seal Safe system rests in a holder on the front panel of the Spectra Optia system. To install the device, do the following:

1. Attach one end of the RF cable to the connector on the Spectra Optia system, and the other end of the cable to the connector on the sealer head. Turn the ends of the cable clockwise on the connectors to lock them in place.
2. Attach a disposable splash guard to the sealer head, if required. For instructions on attaching a splash guard, see page 112.
3. Put the sealer head into the holder. The device is now ready to use.

Caution: To avoid possible damage to the Seal Safe system, always disconnect the sealer head and the RF cable before transporting the Spectra Optia system.

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Operating the Seal Safe System

Perform the following steps to operate the Seal Safe system:

Warning: Ensure that the sealer head and the tubing are free of moisture and debris before using the Seal Safe system.

Warning: Do not seal the tubing within 8 cm (3 in) of the needle, or you may cause a burn at the needle entry point.

Warning: Do not place your fingers within 2.5 cm (1 in) of the Seal Safe system's sealing jaw, or you may receive a radio frequency (RF) burn.

1 Hold the sealer head in the palm of your hand with your fingers on the plastic cover of the lever, so that the jaws open facing upward and you can see the indicator light on the head (Figure 10-1).

Figure 10-1: Hold the sealer head with jaws open facing upward

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2 Place the tubing into the jaw of the head and squeeze the lever until the jaw is completely closed and the indicator light illuminates (Figure 10-2).

Figure 10-2: Hold the jaw closed until the indicator light illuminates

3 After the indicator light goes off, hold the jaw closed for one second, and then release the lever.

4 Remove the tubing and inspect the integrity of the seal.

5 Put the sealer head back into the holder on the Spectra Optia system.

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Cleaning the Seal Safe System

This section contains instructions on how to clean the system. You are required to perform only periodic cleaning of the Seal Safe system.

Cleaning the Jaw Cavity of the Sealer Head

Debris or fluid in the jaw cavity of the sealer head impairs the performance of the device. If the jaw cavity becomes contaminated, clean it immediately by performing the following steps:

1. Disconnect the sealer head from the RF cable.

   Warning: Disconnect the sealer head from the RF cable before cleaning to avoid receiving a serious radio frequency (RF) burn during the cleaning process.

2. Remove and discard the splash guard, if used.
3. Clean the jaw cavity with alcohol applied to a cotton swab. Do not use bleach solution to clean the cavity (Figure 10-3).

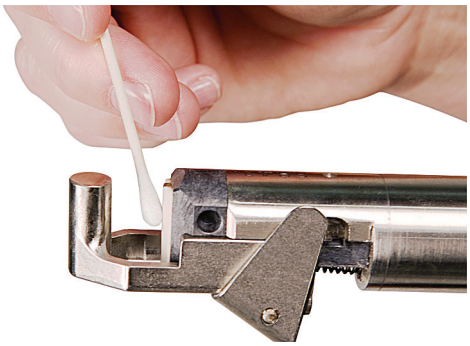

Figure 10-3: Clean the jaw cavity with a cotton swab

4. Clean all areas outside the jaw cavity. Squeeze the lever to expose areas outside of the cavity, and clean those areas.
5. Dry all parts of the jaw and jaw cavity.
6. Reconnect the RF cable, and put the sealer head back into the holder on the Spectra Optia system.

   Note: If you are unable to satisfactorily clean the jaw cavity by performing the steps above, proceed to the instructions below for cleaning the sealer head.

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Cleaning the Sealer Head

The sealer head can be easily disassembled to allow for thorough cleaning and disinfection. Follow the instructions below to disassemble, clean, and reassemble the sealer head.

Disassembling the sealer head

1. Disconnect the RF cable from the sealer head.
2. Remove and discard the splash guard, if used.
3. Hold the sealer head in a vertical position with the jaw end pointing upward, and use your thumb to depress the jaw to the closed position. Do not squeeze the lever. For additional leverage, place the bottom of the of sealer head on a padded surface (Figure 10-4).

Figure 10-4: Depressing the jaw to the closed position

4. Remove the lever by slightly releasing the jaw and pulling the lever down and back (Figure 10-5).

Figure 10-5: Removing the lever

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5 Remove the jaw by pulling it up and sideways (Figure 10-6).

Figure 10-6: Removing the jaw

Cleaning the components of the sealer head

1 After you disassemble the sealer head, clean the components with alcohol applied to a cotton swab. Do not use bleach solution to clean the components.

2 Dry the components with a soft cloth.

3 Reassemble the sealer head, according to the instructions below.

Reassembling the sealer head

1 Ensure that the spring is in place in the head.

2 Locate the grooves on both sides of the head. Align the jaw with the grooves and slide it down the sealer head until it touches the spring (Figure 10-7). Ensure that the spring fits into the indentation in the jaw.

Figure 10-7: Aligning the jaw with the grooves

3 Use your thumb to slightly depress the jaw. Ensure that the spring stays in place.

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4 Replace the lever by tipping it at a 45° angle and positioning the lever pivots behind and below the pivot slots (Figure 10-8).

Figure 10-8: Replacing the lever

5 Push down the lever to engage the lever pivots while simultaneously depressing the jaw with your thumb.

6 Release your thumb. The lever should fully engage and secure the jaw on the sealer head.

7 Squeeze the lever to ensure that the head mechanically functions. If the jaw does not completely close, check the position of the spring.

8 Attach a clean splash guard, if required.

9 Reconnect the RF cable, and put the sealer head back into the holder on the Spectra Optia system.

Attaching a Splash Guard

1 Disconnect the RF cable from the sealer head.

2 Prepare a new splash guard:

   a. Remove the perforated inset from one side of the splash guard (Figure 10-9).

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b. Fold the other inset inward at a 90° angle to form a clip (Figure 10-9).

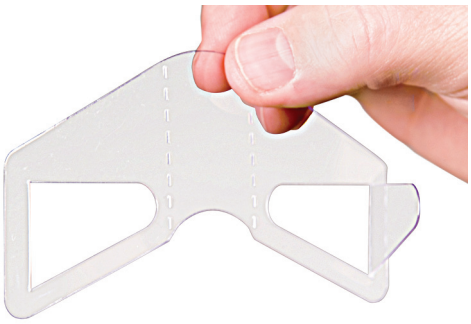

Figure 10-9: Inset folded to form a clip

c. Fold the sides of the splash guard inward at the perforations (Figure 10-10).

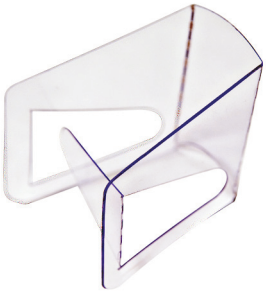

Figure 10-10: Splash guard folded at the perforations

3 Align the splash guard with the lever assembly on the sealer head.

4 Attach the splash guard and use the clip to lock it in place (Figure 10-11).

Figure 10-11: Attaching the splash guard and locking it in place

5 Reconnect the RF cable, to the sealer head and put the sealer head back into the holder on the Spectra Optia system.

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Seal Safe System Specifications

Table 10-1: Physical

Characteristics	Performance
Physical dimensions (sealer head with RF cable)	Diameter: 2.5 cm (1 in) Relaxed length: Approximately 1.1 m (3.7 ft)
Weight	External parts: 0.4 kg (0.9 lb)

Table 10-2: Environmental

Characteristics	Performance
Ambient operating temperature (sealer head with RF cable)	15 °C to 35 °C (59 °F to 95 °F)
Ambient operating humidity	8% to 90% relative humidity (RH), noncondensing
Cleanability	Unit is not damaged by cleaning with alcohol.
Fluid spillage	Unit is not rendered unsafe by saline spillage on the sealer head and RF cable.
Shipping/storage temperature	0 °C to 60 °C (32 °F to 140 °F)

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Glossary of Terms

AC infusion rate — The rate in mL/min/L TBV that anticoagulant is infused to the patient during the run.

ACD-A — An anticoagulant used during apheresis procedures. ACD-A stands for Anticoagulant Citrate Dextrose Solution A.

Albumin — A Plasma protein that helps to maintain fluid balance and to control the viscosity of Plasma.

Allogeneic — In blood transfusion or transplantation, a situation in which the donor and the recipient are different but of the same species.

Alloimmunization — A transfusion complication whereby a recipient develops antibodies toward antigens from a donated blood product.

Anticoagulant (AC) — An agent used to prevent the formation of blood clots.

Antigen — A foreign substance capable of stimulating an immune response when introduced into the body.

Apheresis — A blood component separation procedure in which whole blood is drawn from a patient or donor, and passed through a device that separates the blood into components. Particular components are either removed or collected, and the remaining components are returned.

Autologous — In blood transfusion or transplantation, a situation in which the donor and the recipient are the same.

Bearing — A hard plastic component of the centrifuge loop of the tubing set that connects the loop to the centrifuge arm and to the entrance of the centrifuge loading port.

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Blood component	In apheresis, the RBC, WBC, Platelets, and Plasma,
Blood warmer	A device used to increase the temperature of fluid or blood delivered or returned to a patient.
Bolus	A dose of fluid given to a patient intended to mitigate hypovolemia.
Bone marrow	The spongy tissue inside some bones, which contains stem cells.
Buffy coat	The fraction of blood after centrifugation that contains most of the white blood cells and platelets.
Cassette	A component of the tubing set that snaps onto the front panel of the system and directs the flow of fluid through the set.
Catheter	A tube that can be inserted into a vessel, body cavity, or a duct to allow the flow of blood, injection of fluid, or drainage.
Centrifugation	A process that uses centrifugal force to separate a mixture.
Centrifuge loop	A component of the tubing set. The group of lines that are loaded into the centrifuge.
Channel	A component of the tubing set used to separate a patient's blood into cellular components.
Chamber	A component of the tubing set used for the secondary separation of platelets and target cells. This component is only on the Collection Set.
Circulatory overload	An elevation in blood pressure caused by an increase in blood volume.
Citrate	A salt or ester of citric acid, which is used as an anticoagulant because it binds calcium ion.
Citrate toxicity	Condition that could occur in certain patients as a result of infusion of ACD-A during an apheresis procedure. Mild forms of this condition are generally recognized by peripheral paresthesia, tingling sensations in the extremities, and/or restlessness. Severe forms of this condition can result in significant cardiac dysfunction.
Clotting	The result of activated platelets releasing chemicals that stimulate clotting factors, causing the blood to coagulate.

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Clumping	The result of platelets thickening and sticking together during an apheresis procedure.
Collar	A six-sided plastic component of the centrifuge loop of the tubing set that secures the end of the loop in the centrifuge.
Collect line	A line on the tubing set used to carry collected blood components to the collection bag.
Collection bag	A bag on the tubing set that holds collected blood components. This bag is only on the Collection Set.
Connector	A component of the tubing set that secures the lines where the separated components exit the channel. It may also facilitate separation.
Custom prime	Process of filling the tubing set with specified fluid after priming the set with saline and before starting the run. Useful when treating a patient with a low RBC volume or low TBV to maintain isovolemia.
Default	A setting or value that is preset by the manufacturer, and used by the system in the absence of a selection made by the operator.
Diversion bag	A bag on the tubing set used to capture a skin plug after performing a peripheral venipuncture, or to collect a blood sample. This bag is only on the Collection Set.
Electrolyte	A mineral in blood and body fluids essential to the function of muscle action and other body processes.
Erythrocyte	An RBC.
Erythrocytapheresis	An apheresis procedure used to separate RBC from a patient's blood.
Electrolyte	A mineral in blood and body fluids essential to the function of muscle action and other body processes.
Extracorporeal circuit	All of the tubing that carries the blood outside of the patient's body. This includes the Spectra Optia system tubing set and the tubing set of any other device connected to the set.
Extracorporeal volume (ECV)	The volume of the patient's blood that is outside of the body during an apheresis procedure.
Four-lumen tubing	Lines that comprise the centrifuge loop of the tubing set.

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Fluid shift	A change in the patient's intravascular volume during an apheresis procedure as blood is drawn, one or more components are retained, and the remaining components are returned, with or without replacement fluid.
Fraction of cells remaining (FCR)	The desired percent of starting defective RBC remaining in the patient's blood at the end of a RBC exchange procedure.
Functionally-closed system	A blood collection system that uses sterile barrier filters to prevent bacteria from entering the system.
Gear train	A component of the centrifuge chamber comprised of a series of rotating gears that keep the filler and the centrifuge arm spinning at the proper speed.
Graft-vs.-Host disease	A condition that occurs when cells from a transplanted organ or tissue attack the cells or tissue of the transplant recipient.
Granulocyte	A type of WBC.
Hct	The abbreviation for hematocrit.
Hematoma	A localized collection of blood in an organ, space, or tissue due to a break in the wall of a blood vessel.
Hgb	The abbreviation for hemoglobin.
Hemolysis	A disruption of the RBC membrane, causing the release of hemoglobin.
Hemostat	An instrument used to compress a bleeding vessel or to stop the flow of fluid through a tube.
Inlet:AC ratio	The ratio of the inlet pump flow rate to the AC pump flow rate, expressed as parts of inlet volume to one part of anticoagulant.
Inlet access	Refers to the patient access from which whole blood is drawn.
Inlet flow rate	The speed at which blood is drawn from the patient.
Inlet line	A line on the tubing set used to carry anticoagulated blood from the patient to the channel.
Inlet pressure	The force per unit of area on the blood flow as it is drawn from the patient.
Interface	The common boundary between blood components separated during an apheresis procedure.

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IP (Internet Protocol) address	A numerical identifier for a computer or a device on a network, which enables communication among the devices on the network.
IV	The abbreviation for intravenous.
Leukapheresis	An apheresis procedure used to separate WBC from a patient's blood.
Leukemia	A cancer of the blood-forming cells in the bone marrow.
Lymphocyte	A type of WBC.
Malaria	A disease caused by a parasite and usually transmitted through a mosquito bite, which infects the RBC.
Manifold	A component of the tubing set. Connector with multiple ports used to join a line with one or more other lines. It may also include an injection site.
Manual rinseback	A process whereby the operator performs rinseback, not the system, in case of a power or system failure.
MNC	Abbreviation for Mononuclear Cell or Mononuclear Cells. MNC are a type of WBC.
MNC collection	An apheresis procedure used to collect MNC from a patient.
Obstruction	An object or a condition that restricts the flow of fluid through the tubing set.
Packed RBC	RBC with most of the Plasma removed.
Packing factor	The relationship between the inlet flow rate and the centrifuge speed, which indicates the degree of separation of the blood components during an apheresis procedure.
Paresthesia	A tingling sensation around the mouth, which is a symptom of citrate toxicity or hypocalcemia.
Patient access	Refers to the device used to gain entry to a patient's venous system.
Peripheral blood	The blood in a vein or artery.
Peripheral blood stem cell	A stem cell that circulates in the peripheral blood.
Plasma	The fluid portion of the blood, which transports proteins and enzymes through the body.

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Plasma bag	A bag on the tubing set that holds collected plasma. This bag is only on the Collection Set
Plasma line	A line on the tubing set used to carry concurrently collected Plasma to the Plasma bag. This line is only on the Collection Set.
Plasmapheresis	An apheresis procedure used to separate Plasma from a patient's blood.
Platelet	A small cell fragment that aids in blood coagulation by helping to repair damage to walls of blood vessels.
Port number	A numerical identifier used for the transmission of data between devices in a network.
Prime	The process of pumping saline through the tubing set to prepare the set for the run.
Procedure	The series of steps performed to accomplish apheresis on the Spectra Optia system. A procedure starts when the procedure is selected and ends when the patient is disconnected.
Radio frequency	Any frequency within the range which radio waves are transmitted.
RBC	The abbreviation for Red Blood Cell or Red Blood Cells. RBC carry oxygen to and carbon dioxide from the tissues of the body.
Red Blood Cell depletion	A type of Red Blood Cell Exchange procedure in which excess or defective RBC are removed from a patient, and replaced with desired replacement fluid.
Red Blood Cell depletion/ exchange	A type of Red Blood Cell Exchange procedure that consists of a depletion procedure followed by an exchange procedure.
Red Blood Cell Exchange (RBCX)	An apheresis procedure in which defective RBC are removed from a patient and replaced with healthy donor RBC.
Remove bag	A bag on the tubing set that holds the removed blood components. This bag is only on the Exchange Set.
Remove line	A line on the tubing set used to carry removed blood components from the channel to the remove bag. This line is only on the Exchange Set.

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Replace line	A line on the tubing set used to carry replacement fluid from the replacement fluid container to the reservoir.This line is only on the Exchange Set.
Replacement fluid	The fluid given to the patient during an exchange procedure to replace the blood components removed.
Reservoir	The component of the tubing set cassette that contains the fluid to be returned to the patient.
Reservoir filter	200-micron filter located at the exit of the reservoir used to filter the fluid returned to the patient.
Return access	Refers to the patient access through which blood components and fluids are returned.
Return flow rate	The speed at which blood is returned to the patient.
Return line	The line that carries fluid from the reservoir to the patient.
Return pressure	The force per unit of area on the blood flow as it is drawn from the patient.
Rinseback	The process that clears the channel of remaining cells and returns them to the patient after the run.
Run	The procedure state that starts when the patient is connected and ends when the run targets are attained, during which apheresis is performed.
Saline	A sterile 0.9% sodium chloride and water solution used to prime the tubing set and to perform an apheresis procedure.
Saline rinse	The process that rinses the tubing set with saline before the run to clear the set of any residual ethylene-oxide, a by-product of sterilization.
Sickle cell disease	An inherited blood disorder that affects the hemoglobin in RBC.
Spillover	A term used to indicate that some RBC from the channel have entered the Plasma line.
Stem cell	An unspecialized cell capable of renewing itself through cell division, or of being induced to become a tissue-specific or organ-specific cell.
System reset	The process that occurs when the system restarts itself after a power interruption or under certain alarm conditions.

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Therapeutic apheresis	An apheresis procedure used to remove a pathological blood component in order to treat a patient.
Therapeutic plasma exchange (TPE)	An apheresis procedure in which Plasma is removed from a patient and replaced with new Plasma or a compatible replacement fluid.
Total blood volume (TBV)	The entire volume of the patient's circulating blood, including the Plasma and the cellular components.
Uticaria	A temporary skin condition caused by allergic reaction, and characterized by a rash and severe itching.
Vascular access device	A type of catheter used to access to the central venous system of a patient.
Vent bag	A bag on the tubing set that holds air displaced from the system.
WBC	Abbreviation for White Blood Cell or White Blood Cells. WBC are cells of the immune system that help the body fight infection.

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Essentials Guide

Spectra Optia®

Apheresis System

ESSENTIALS

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