



RED BLOOD CELL EXCHANGE

ADVANCING THERAPEUTIC APHERESIS AND CELL COLLECTIONS TO THE NEXT LEVEL OF PATIENT CARE

TERUMOBCT
Unlocking the Potential of Blood

SPECTRA OPTIA® APHERESIS SYSTEM

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.

INDICATION FOR USE

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

Custom prime option	Clearly defined custom prime sequence is differentiated from the procedure and from the end run values
Dedicated procedures: exchanges, depletions and depletion/exchanges	System only requires inputting data specific to the procedure selected
Fraction of cells remaining (FCR) calculation	Eliminates the need to manually calculate the target FCR
Anticoagulant (AC) management	The citrate in the replacement fluid is taken into consideration when calculating the AC infusion rate Lengthy manual calculations not required to determine the AC infusion rate Allows direct control of AC infusion rate to manage citrate toxicity
Data entry	System prompts the operator for the data needed for the selected procedure If procedure targets cannot be attained, system will recommend alternate procedure targets
Rinseback option	System defaults to no rinseback but provides the option to perform rinseback if necessary

SYSTEM PERFORMANCE IN PATIENTS WITH SICKLE CELL DISEASE

The data below demonstrates how the Spectra Optia system accurately predicts the FCR and the final patient hematocrit (Hct).

PARAMETERS AND STATISTICS	
Actual to Calculated FCR Exchange, Depletion/Exchange Procedures (N=60)	
Mean ± standard deviation	0.90 ± 0.16
Median (minimum, maximum)	0.92 (0.0, 1.3)
95% CI	0.86, 0.94
Actual to Calculated FCR Depletion/Exchange Procedure (N=16)	
Mean ± standard deviation	0.89 ± 0.15
Median (minimum, maximum)	0.91 (0.6, 1.1)
95% CI	0.82, 0.97
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

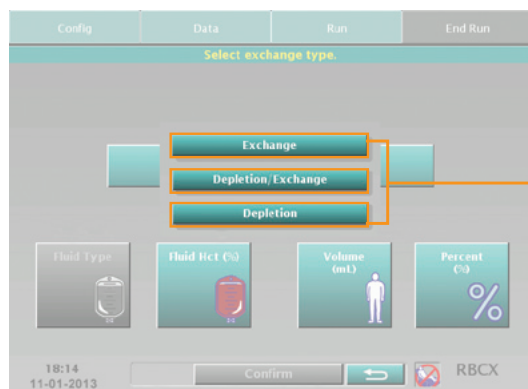
CI = confidence interval

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. The primary endpoint for the study was the mean ratio of the actual fraction of cells remaining. The secondary endpoint was the Spectra Optia system's ability to achieve the desired final Hct.

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 performed.

How it works

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.



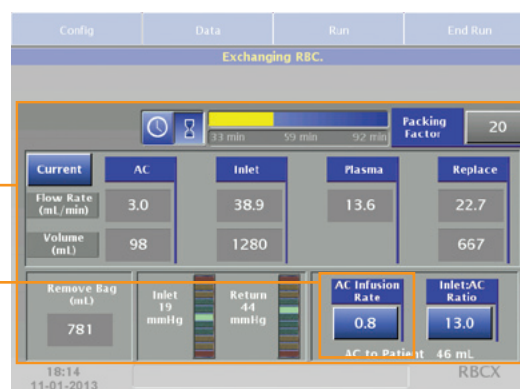
PROCEDURE TYPE SCREEN

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.

AC infusion rate can easily be monitored and modified throughout the procedure.



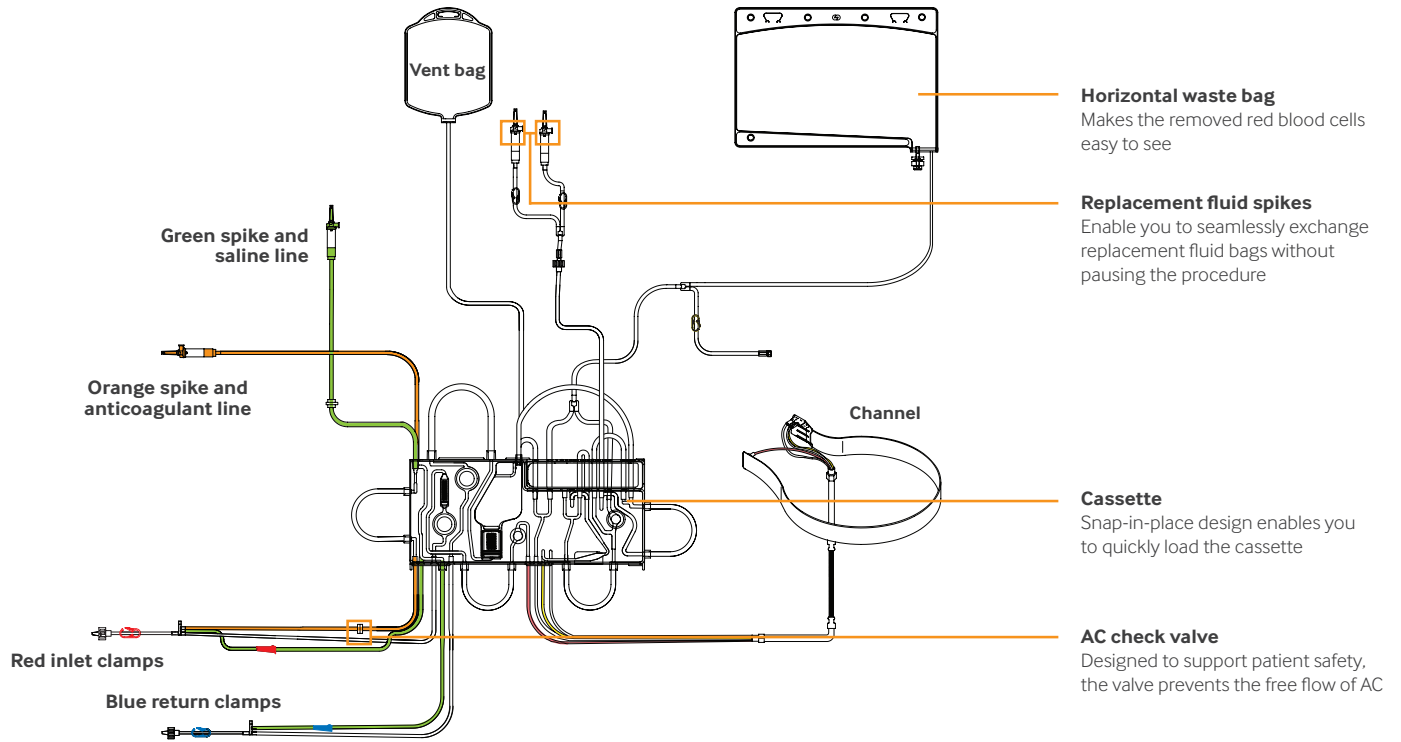
RUN VALUES SCREEN

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.

COMPARISON TO COBE® SPECTRA APHERESIS SYSTEM

COBE SPECTRA SYSTEM	SPECTRA OPTIA SYSTEM
Complex depletion/exchange procedure	Dedicated procedure with streamlined workflow
Blood prime not differentiated from the procedure	Clearly defined custom prime sequence is differentiated from the procedure and end run values
Extracorporeal volume (ECV) = 285 mL	ECV = 185 mL maximum
Operator must remember data to enter for select procedures	System will automatically prompt operator for needed data to perform selected procedure
Manual FCR calculation	Option of automated FCR calculation or manual FCR calculation
System defaults to deliver rinseback; operator must manually skip rinseback if not desired	System defaults to no rinseback and provides rinseback option, if necessary
AC infusion rate is not displayed and manual calculations are required for end of run AC data	AC infusion rate and end of run AC data is displayed

EXCHANGE SET



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)

For a complete statement of the indication and listing of the relevant contraindications, warnings and cautions associated with the red blood cell exchange protocol, please refer to the appropriate Spectra Optia Apheresis System manuals.

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
- Clinical support
- Users groups and professional networks
- Technical support
- Customer support

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