



**FRESENIUS
KABI**

caring for life



Amicus

Therapeutic Plasma Exchange

Patient Study: A multicenter, randomized, non-blinded, cross-over paired evaluation of Amicus and COBE Spectra®

There were no clinically significant differences seen between Fenwal Amicus and COBE Spectra in a number of laboratory measurements including complement activation, coagulation cascade activation and hematologic variables.

Plasma removal efficiency: >80%

Mean Procedure Time: 103.9 min

Fluid balance accuracy: 99.8%

Anticoagulat to the patient: 126mL



Amicus Therapeutic Plasma Exchange

Fenwal Amicus delivered high plasma removal efficiency which resulted in less AC to the patient.

	Amicus n = 30 mean ± SD	COBE Spectra N = 30 mean ± SD	P - value [‡]
Patient			
Weight (kg)	91.6 ± 20.0	91.2 ± 19.4	0.52
Height (cm)	174 ± 12	174 ± 12	-
Blood Volume (mL)	5,329 ± 1,039	5,314 ± 1,030	0.52
Pre-procedure Hct (%)	36 ± 5	36 ± 6	0.88
Procedure			
Procedure time (min)	103.9 ± 30.8	110.5 ± 27.1	<0.001
WB Volume Processed (ml)	7,159 ± 1,908	7,730 ± 1,858	<0.0001
AC Used (mL)	577 ± 164	598 ± 144	0.0004
Volume Processed - AC (mL)	6,583 ± 1,745	7,132 ± 1,714	<0.0001
Plasma Processed (mL)	4,257 ± 1,151	4,578 ± 1,012	<0.001
Plasma Removed (mL)	3,459 ± 840	3,448 ± 849	0.70
Plasma Collect Rate (mL/min) [†]	34.2 ± 6.8	31.8 ± 6.1	0.00056
Results			
PRE (%)	81.9 ± 7.6	75.2 ± 6.3	<0.00001
Replacement Fluid to Patient (mL)	3,438 ± 830	3,524 ± 838	0.0422
AC to Patient (mL)	126 ± 86	144 ± 53	0.008
Fluid Balance Accuracy (%)	99.8 ± 0.2	98.8 ± 1.8	<0.0001
Waste Plasma Free Hb (mg/dL) [†]	0.51 ± 0.62	0.80 ± 2.05	0.91
Waste Plasma PLT (x10 ¹⁰)	3.59 ± 2.07	3.66 ± 2.83	0.39
Platelet CE1 (%)	11.10 ± 4.2	11.23 ± 4.6	0.64

Refer to the Amicus Separator operator's manual for the full list of warnings and cautions associated with the use of the Amicus device.

‡ Wilcoxon signed-rank test used to compute p value for nonparametric data. Paired t test used for all other p values.

† Only 29 pairs were available for evaluation.

|| Only 26 pairs were available for evaluation.

Note: Reinfusion volume of approximately 200mLs was not included in fluid balance for COBE Spectra.

Source: Winters JL et al. A multicenter evaluation of a new therapeutics plasma exchange procedure. Transfusion 2013;53:3269-3278.

Cobe Spectra is a registered trademark of Terumo BCT, Inc.