COM.TEC Therapeutic Plasma Exchange (TPE)

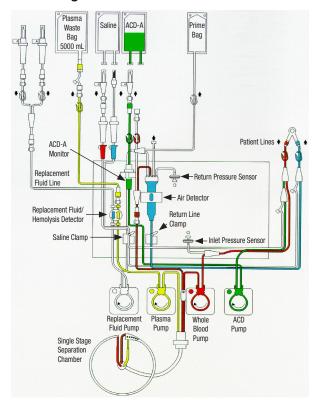


COM.TEC Kit Performance Report

Important: If reaction or injury has occurred call Fresenius Kabi Product Complaint and Support at 1-800-933-6925.

Incident Date:	Instrument S/N.	Software Version:			
UDI No.:		Product Co	ode: L	Lot No.:	
When Was the Problem Detect	ed?				
☐ Set Up ☐ Prime%	□ Exchange	\square Reinfusion	☐ After Procedure/G	OC.	
Problem Type (Mark all applicated Alarms (Specify) ☐ Cracked ☐ Excess Air					
Please answer following questi 1. Was there any adverse event 2. If applicable, list name of any 3. Was the procedure successfu 4. If no, was the procedure stop 5. Was product lost? Yes Check box if you do NOT wish to	or injury, or any the drug administered lly completed? Ye ped due to a soft	d: es □ No □ N// goods incident	4 🗆		

Please circle specific components on the diagram where incident occurred



Additional Problem Description / Explanation

Kit Return To Fresenius Kabi 1. Sample available for evaluation? Yes \(\) No \(\) 2. Sample return box needed? Yes \(\) No \(\) Return label only \(\) 3. Picture available for evaluation? Yes \(\) No \(\) Please e-mail a clear picture along with this report to MDComplaintSupport@Fresenius-kabi.com Center Authorized Signature/Date: Customer Information The following information Facility Name: \(\) Contact Person: \(\) Account Number: \(\) Operator Name: \(\) City/State/Zip: \(\) Phone Number:

Fax this report to 1-888-858-2983 or E-mail to MDComplaintSupport@Fresenius-kabi.com and include a copy of this form when returning a kit.

Customer Information (please print)The following information is required to receive a credit