Whole Blood Performance Report

FRESENIUS KABI

Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.

Incident Date: _____ Lot No.: _____ UDI No. (if applicable): _____

Product Code: _____ Filter No.: _____

When Was the Problem Detected?

☐ Before Use ☐ After Donation (at collections) ☐ Centrifugation ☐ Storage (of collected product)

☐ Donation ☐ Filtration ☐ Plasma Expression ☐ From Hospital ☐ Other (specify)_____

Problem Type (*Mark all applicable*) ☐ Discolored ☐ Flat ☐ Leak (solution) ☐ Mis-assembled ☐ Pre-activated Cannula

☐ Broken ☐ Cut/Slice ☐ Hole ☐ Dull/Drag ☐ Kink ☐ Leak (blood) ☐ Excess Moisture ☐ Blocked/Restricted

☐ Missing ☐ Difficult to Break ☐ Illegible ☐ Bent ☐ Separated ☐ Particulate Matter ☐ Other (specify) _____

Please answer the following questions:

1. Was there any adverse event or injury? Yes ☐ No ☐
2. Was the procedure successfully completed? Yes ☐ No ☐ N/A ☐
3. If no, was the procedure stopped due to a soft goods incident? Yes ☐ No ☐ N/A ☐
4. Was product lost? Yes ☐ No ☐ N/A ☐

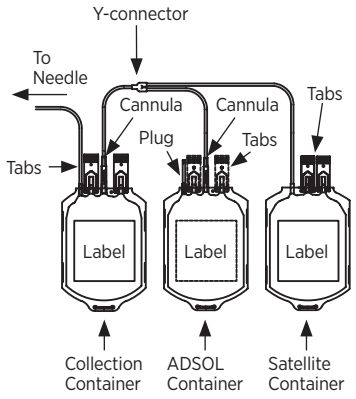
Check box if you do **NOT** wish to receive response letters. ☐

E-mail address for letter recipient (if applicable)

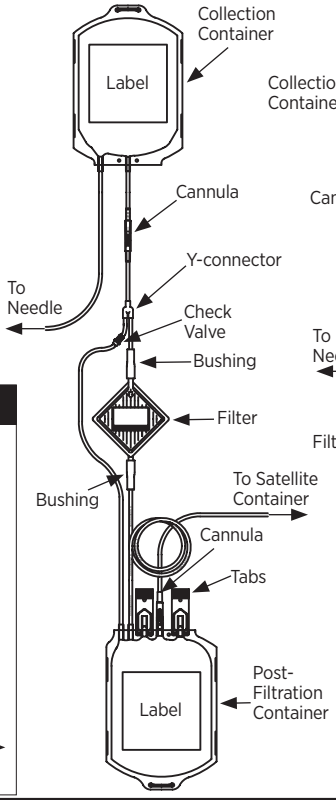
Please circle specific components on the diagram where incident occurred

BPU Configurations

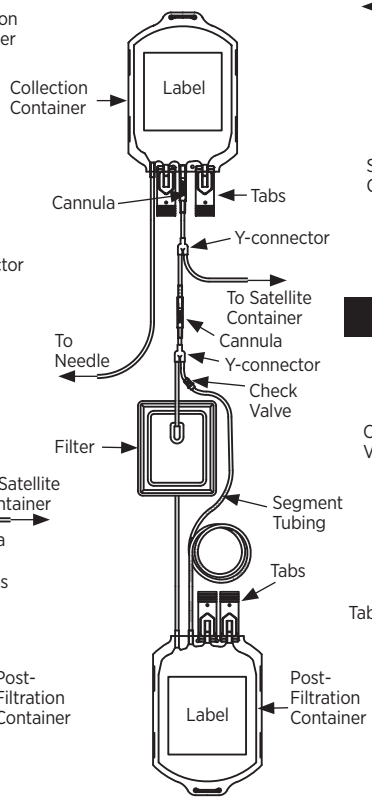
BPU Without Filter



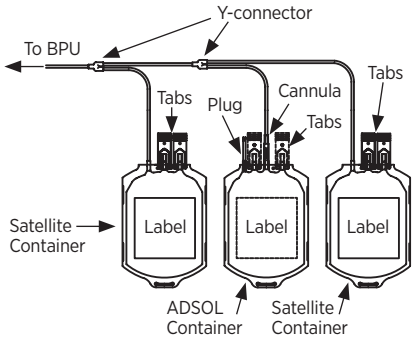
BPU With Integral Whole Blood Filter



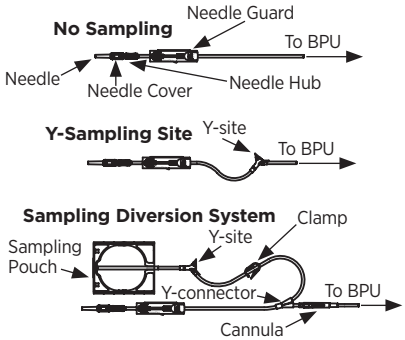
BPU With Integral RBC Filter



Satellite/Secondary Containers

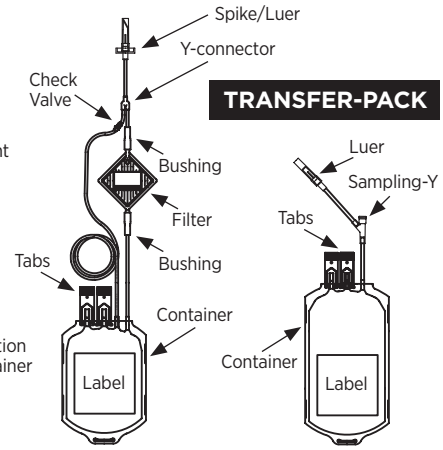


Needle/Sampling System



Sterile Connect Filter

TRANSFER-PACK



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 **mdpmqa.usa@fresenius-kabi.com**

Center Authorized Signature/Date:

Customer Information (please print)

The following information is required to receive a credit

Facility Name: _____

Contact Person: _____

Account Number (if known): _____

Operator Name: _____

Street Address: _____

City/State/Zip: _____

Phone Number: _____

Contact Person's E-mail: _____

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