

Blood-Pack Unit with Fenwal Bioflex RC Performance Report



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

Incident Date: _____ Lot No.: _____ Product Code: _____
 Filter No.:* _____ Donor Bleed/ID No.: _____

*Note: Number may be found on filter skirt below inlet (branded) side of filter

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:

- Was there any adverse event or injury? Yes No
- Was the procedure successfully completed? Yes No N/A
- If no, was the procedure stopped due to a soft goods incident? Yes No N/A
- 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)

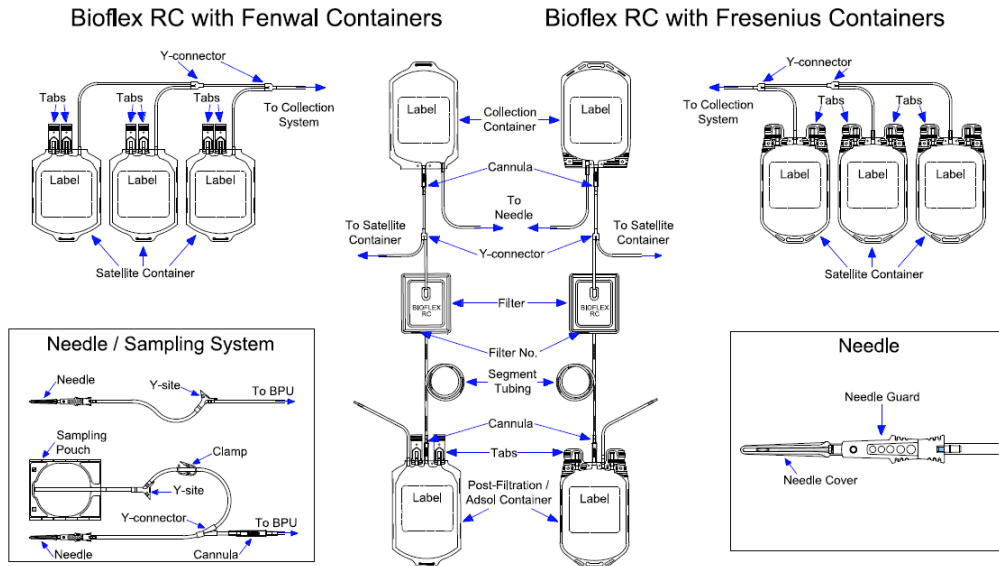
If filter related issues, please provide feedback or circle a response below, as applicable:

- How were the filters processed: RT or Cold? _____
- Which centrifuge cup/liner was used? _____
- How long was the filtration time? _____
- How much blood, relatively speaking, was left in the primary bag at the time of the incident? _____
- Was the filter inlet side flat or filled at the time of the incident: Flat or Filled? _____
- (circle one) If WBC failure, what was the actual value _____

If Needle related issues, please select the applicable answer below:

- When was the condition detected?
- Removal from Foil Pouch During Labeling
 After Labeling Removal of Needle Cover
(at the time of phlebotomy)
- Notes:**
- When performing QC testing, please retain the entire BPU until testing is completed and is passing.
 - QC samples if failed should be returned in their entirety (primary container filter and RBC container).

Please circle specific components on the diagram where incident occurred



Additional Problem Description / Explanation

Kit Return To Fresenius Kabi

- Sample available for evaluation? Yes No Not Required
 - Sample return box needed? Yes No Return label only
 - 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.