

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:

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)

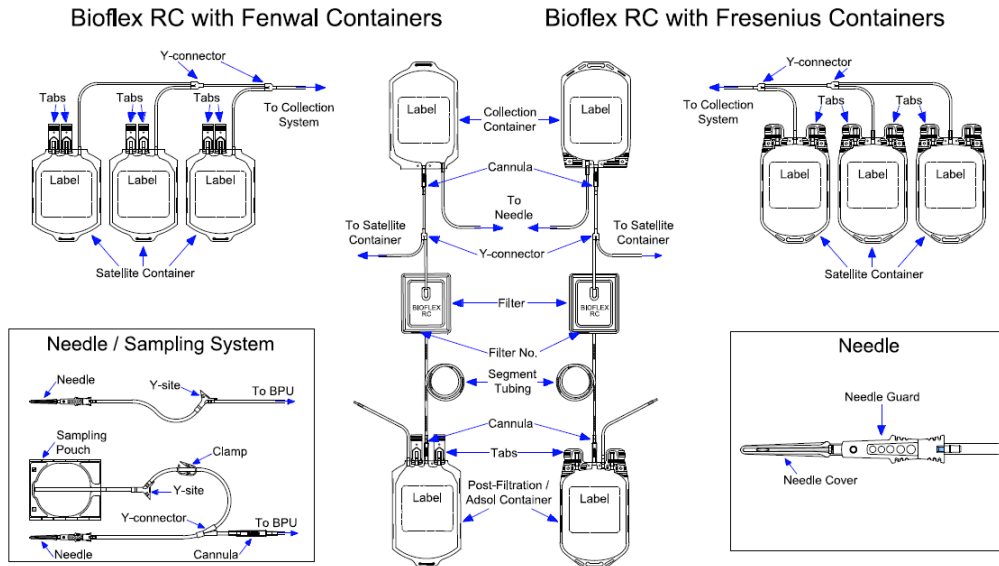
If filter related issues, please provide feedback or circle a response below, as applicable:

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

1. Sample available for evaluation? Yes No Not Required
 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.