

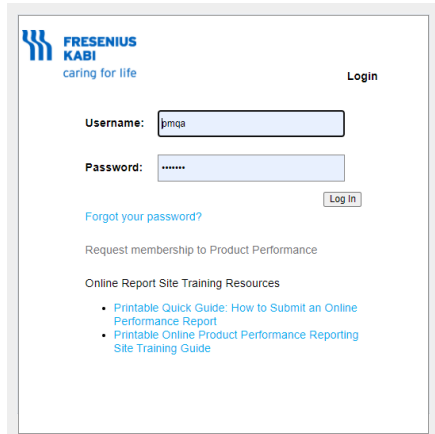
Online Product Performance Reporting Training Guide

Electronic product performance reporting

- Simple online entry and submission
- Easy to save forms with image upload option and printing capabilities
- Reporting feature provides historical reviews and status updates

Getting Started

- Step 1 – Go to the following link: <https://productperformance.FreseniusKabiUSA.com>
- Step 2 – Complete enrollment screens (shown below)
- Step 3 – Receive email confirmation requesting account information
- Step 4 – Reply with confirmation of address and location of center
- Step 5 – Receive email confirmation with username and password



[Product Performance](#) [Search](#) [Change Password](#) [Log Out](#) [Learning Modules](#)

If you would like to set up an account on Fresenius Kabi's Product Performance site, please fill out the form below. When you submit, your account will go through a review process, where it will be matched and assigned against your companies' accounts. You will receive an email when your account is approved.

Be sure to use a valid email address format.

User Name:

First Name:

Last Name:

Email:

Picture: Type the characters in the picture below.



The picture contains 6 characters.

Characters:

[Can't see the word?](#)

Select Product Performance: Select appropriate product line

Product Performance Search Change Password Log Out Learning Modules

Product Performance for Disposables

Submit a Disposable Performance Report

Select a Product Line to begin a Performance Report submission:

Medical Device Disposables:

Agilia
Alyx
Amicus
Aurora XI
Autopheresis-C or Aurora
Solution Only
Bioflex RC BPU
COM.TEC
iNfusia
Mononuclear Cell (MNC)
Therapeutics (TPE/RBCX)
Whole Blood

Fresenius Kabi takes quality seriously. If you need to return a product because of a quality issue, please complete the appropriate product performance report form.

Important: If reaction or injury has occurred, or you need additional assistance, please call Fresenius Kabi Product Complaint and Support immediately.

In the US call	In Europe call
1.800.933.6925	+32.0.1048.2833 (English)
	+32.0.1048.2825 (French)
	+32.0.1048.2835 (German)

If you need to update your location, email address, or phone number, please email us at mdcomplaintsupport@fresenius-kabi.com. Please provide your username and the updates you require.

Laboratory Device Disposables:

If you wish to report a Laboratory Device Disposable quality issue, please visit our site at <https://www.fresenius-kabi.com/us/report-a-medical-device-product-quality-issue> under Laboratory Device Disposables.

Product Performance Search

Looking for a recently submitted Performance Report?
Use the [Performance Report Search](#) to find it.

Fresenius Kabi

Your Account's Performance Report Summary:

Entering a Report: Account Information and General Incident Information

1. Select your Account Number (any field with an * is required for submission)
2. Fill out the General Incident Information as required

Account Information

* Account:

Customer Reference Number:

If desired, provide your internal identifier number within this field

QA Contact:

Please provide the name of the person that has knowledge of the report and is able to provide additional information if requested.

General Incident Information

Please check if the answer is YES

Did the issue occur during a donation?:

Was there any adverse event or injury?:

*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

3. If the box is checked yes for “Was there any injury or adverse donor reaction?” a required field will populate for an explanation of the reaction

General Incident Information

Did the issue occur during a donation?:
Was there any adverse event or injury?: *Please check if the answer is YES*

* Please describe event:

*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

Entering a Report: Correspondence Information (if applicable)

1. Check box if you do NOT wish to receive a response letter
2. If you do require a letter, enter the email address the letter should be sent to **IF** different from the person submitting the complaint

Correspondence Information

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

* E-mail address of letter recipient
if different from the person submitting the report (if the same, check N/A): N/A

Entering a Report: Product Details

1. Enter in the Incident Date, Product Code, and Lot Number
2. Fill in rest of fields (as applicable)

Product details section will vary depending on product line selected

Product Details

* Incident Date:

* Product Code: [Add a Product Code](#)

* Lot Number:

Number of Incidents:

Instrument Serial Number:

Software Version:

Volume of Plasma Collected (mL):

Batch Tag Time (hh:mm:ss):

Batch Tag Number:

Video Jet Number:

Donor Bleed Number: * This field is required

Entering a Report: Problem Details

1. Select when incident occurred (drop down menu)
2. Select what the issue was (drop down menu). If the choice you select states "Please Specify" please enter the issue that occurred in the empty field as seen below (example: bent, poor fit, etc.)

Problem Details

* When was the problem detected?: Collection Cycle ▼

Please specify value if requested: 2

* Identify the problem type: Cut / Slice ▼

Please specify value if requested:

Entering Report: Problem Location

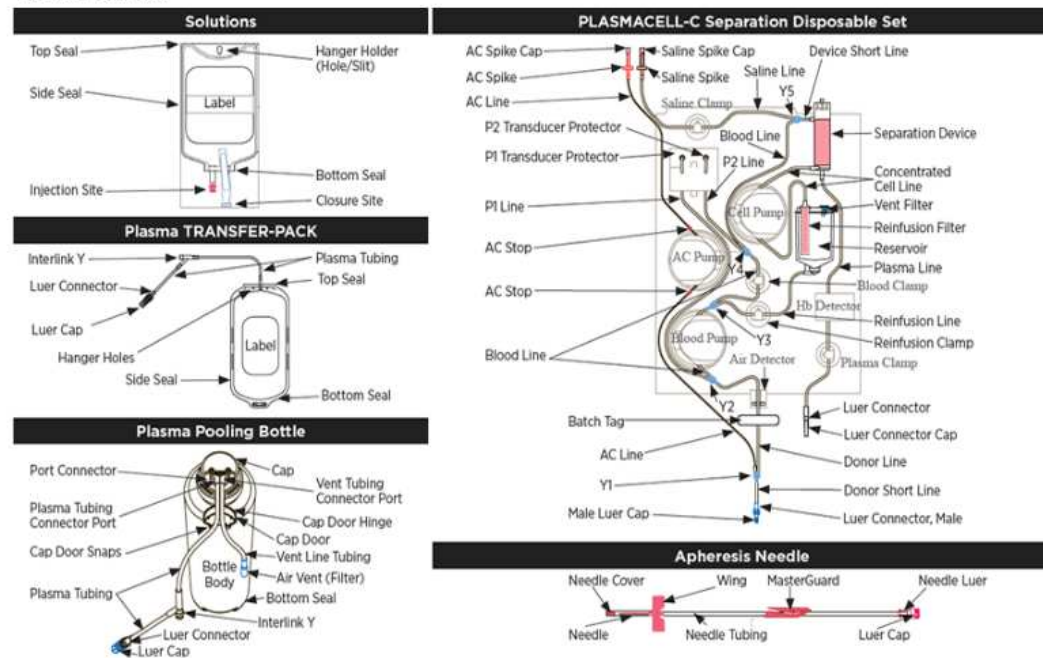
1. Indicate the area where the problem occurred
To select, click on the name of the item, not on the picture

This diagram will vary depending on the product line chosen

* Please select the location of the specific component on the diagram where the issue occurred.
If the location is not known, please check this box:

The below diagram allows only ONE component to be selected. If you have multiple components to report, please include the additional components within the Additional Incident Description section.

Selected Location:



2. If the location is unknown or not on the diagram please select the checkbox and include the location in the "Additional Incident Description" box below the diagram

Entering Report: Additional Incident Description

1. If there is any additional information you'd like to provide please enter it within the "Additional Incident Description" box as seen below

Additional Incident Description:

Entering Report: Product Return Details

1. If you would like to return the sample, check the box next to "Would you like to return the sample for evaluation?"
2. When the above box is checked, the following question will populate "Is a sample return box needed?" along with a note concerning return labels (see below)
3. When the above box is checked, the following statement will populate "If the address to ship the box to is different than the account address: **ACCOUNT ADDRESS** Please provide the ship to address here:

Product Return Details

Please check if the answer is YES

Would you like to return the sample for evaluation?:

Is a sample return box needed?: If no box is required, a new return label will be emailed to you separately once the complaint is processed. If a sample box is required, a return label will be included in the sample return box.

If the address to ship the box to is different than the account address :
please provide the ship to address:

If you have a picture available of the defective product, please attach it: No file chosen

4. If you have pictures of the incident, you can upload them by clicking on browse. (If you have multiple pictures to upload, you must create a compressed zip file or add the pictures to a word document before uploading)
*The name of the file should contain **ONLY** letters and numbers. Any special characters such as, "#" will cause the report to submit without the picture and will not provide a confirmation page*

Report Submission

1. Click "Submit" to submit your report
2. The following screen will populate. The submission number can be found under the submission details

Plasmacell-C Product Performance Report

Account Details Account: 60025148 Account Name: QA Contact: Sarah Hoke Submitted By: Elizabeth Kendall Work Phones: Fax: Email:	General Incident Information Was there any adverse event or injury?: No Was this procedure successfully completed?: No Was procedure stopped due to a soft goods incident?: No Was product lost?: No Product Details Product Line: Autopheresis-C Product Code: 2B1323N Lot Number: C940882 Number of Incidents: 1 Instrument Serial Number: Software Version: Batch Tag Time: Batch Tag Number: Video Jet Number: Volume of Plasma Collected (mL): Donor Bleed Number:	Product Return Details Would you like to return the sample for evaluation?: No Is a sample return box needed?: No Problem Details When was the Problem Detected?: Set Up Identify the Problem type?: Missing (not in box) Problem Location: Closure Site Attachment File Name: <u>Additional Incident Description:</u>
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Solutions **PLASMACELL-C Separation Disposable Set**

Top Seal Hanger Holder (A/B/C/D) AC Spike Cap Saline Spike Cap Device Short Line

3. If you desire, you can print this page by clicking the "Print Page" button in the upper right corner, or you can click on "Submit a New Form" to submit another report

How to Search for Product Performance Reports

1. Click on Search

Product Performance **Search** Change Password Log Out Learning Modules

Product Performance for Disposables

Submit a Disposable Performance Report

Select a Product Line to begin a Performance Report submission:

Medical Device Disposables:

[Agilia](#)
[Alyx](#)
[Amicus](#)
[Aurora Xi](#)
[Autopheresis-C or Aurora Solution Only](#)
[Bioflex RC BPU](#)
[COM.TEC](#)
[INFusia](#)
[Mononuclear Cell \(MNC\)](#)
[Therapeutics \(TPE/RBCX\)](#)
[Whole Blood](#)

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Product Performance Search

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Fresenius Kabi

Your Account's Performance Report Summary:

2. Choose Account Number

3. You can search by date, product line, product code, lot number

4. OR you can search by submission number, customer reference number, or notification number

5. Once your parameters are entered click "Search"


Use the form below to search for submitted product performance reports.


Search Performance Report

Choose an Account

* Account:

Search By Date

* From Incident Date: 

* To Incident Date: 

Product Line:

Product Code:

Lot Number:

Search By Identifier

Choose one of the options below:

Submission Number

Customer Reference Number

Notification Number

Search Results

1. All the reports within the parameters you set will populate



Product Performance Search Change Password Log Out Learning Modules

Search Result

Submission Number	Account Number	Account Name	QA Contact	Product Line	Incident Date	Product Code	Product Description	Lot Number	Problem Detected	Problem Type	Status
32683	60025148		Sarah Hoke	Autopheresis-C	7-08-2014	2B1323N	0.9% SOD CHL INJ, USP (AUTO-C)	C940882	Set Up	Missing (not in In box)	In Progress

Export to Excel

2. Click on Export to Excel if you wish to view the results in Excel

	A	B	C	D	E	F	G	H	I	J	K	L
1	Product Performance Search Result											
2												
3	Submission Number	Account Number	Account Name	QA Contact	Product Line	Adverse Event	During Donation	Donation Completed	Product Lost	Soft Goods Issue	Incident Date	Drug Administered
4	127921	60013057			Autopheresis-C	No	Yes	No	Yes	Yes	2/28/2019	

3. Click on the Submission Number if you wish to view the individual report in more detail

Corrections

- If you need to make corrections to a report please call Product Complaint and Support (PCS) at 800-933-6925 or email PCS at mdcomplaintsupport@fresenius-kabi.com
- Provide the submission number, your full name, and changes that need to be made

Refer to the Instructions for Use and Operator's Manual for a complete list of warnings and precautions associated with the use of these products.