

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

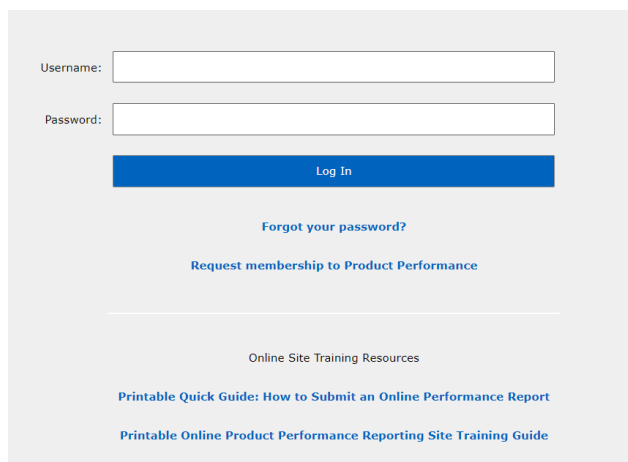
Getting Started

Step 1 – Go to the following link: <https://productperformance.FreseniusKabiUSA.com>

Step 2 – Click on “Request membership to Product Performance”

Step 3 – Complete enrollment screen (shown below). Ensure you include the correct phone number and address, so you are associated with the correct account

Step 4 – Receive email confirmation with username and password



Username:

Password:

[Log In](#)

[Forgot your password?](#)

[Request membership to Product Performance](#)

Online Site Training Resources

[Printable Quick Guide: How to Submit an Online Performance Report](#)

[Printable Online Product Performance Reporting Site Training Guide](#)

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:

*Phone: () - -

*Address:

Account # (if known):

[Create User](#)

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

If the box is checked yes for "Was there an adverse event or injury?" a required field will populate for an explanation of the event

Account Information:

* Account:

Select An Account

Customer Reference Number:

If desired, provide your internal identifier number within this field

QA Contact:

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

General Incident Information:

Did the issue occur during a donation?
(check if yes)

Was there an adverse event or injury?
(check if yes)

* Please describe the 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 the product lost?

 Yes No N/A

Entering a Report: Correspondence Information (if applicable)

1. Check box if you do NOT require a response letter
2. If you do require a letter, enter the email address IF different from the person submitting the complaint

Correspondence Information:

Check box if you do NOT require a response letter:

* E-mail address of letter recipient:

N/A

If different from person submitting the report (if the same, check 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:

* Re-enter Lot Number:

* Number of Incidents:

Instrument Serial Number:

Software Version:

Product Collected (ml):

Donor Bleed Number:

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

Problem Details:

* When was the problem detected?

* Identify the problem type:

Entering Report: Problem Location

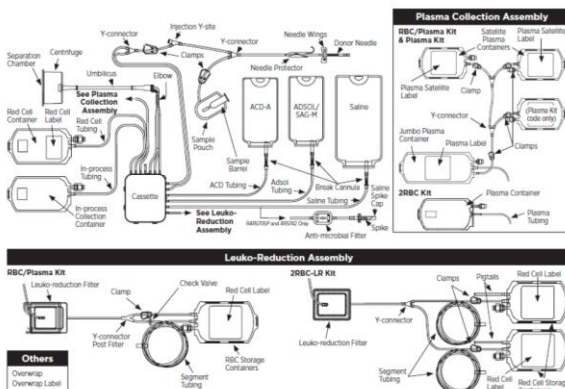
1. Indicate the area where the problem occurred
To select, click on the name of the item, not on the picture

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. 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.

If the location is not known, please check this box:

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 Yes box next to "Is a sample available for evaluation?"
2. When the Yes 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 sample needed 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:"
4. If you have pictures of the incident, you can upload them by clicking on browse

Product Return Details:

* Is a sample available for evaluation?

Yes

No

Not
Required

Is a sample return box needed?

(check if yes)

If the address to ship the box to is different than the account address : Fresenius Kabi - Lake Zurich - Three Corporate Drive please provide the ship to address:

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 you have pictures of the defective product, please attach them:

No Files Chosen

Browse

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

Alyx System Kit Performance Report

Submit a new form Print

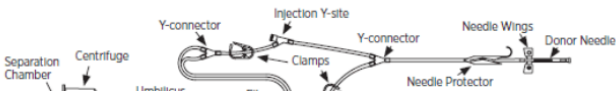
Account Details Account Account Name Account Address QA Contact Submitted By Work Phone Fax Email	General Incident Information Did the issue occur during a donation? Was there any adverse event or injury? Was the procedure successfully completed? Was the procedure stopped due to a soft goods incident? Was the product lost?	Product Return Details Email address for letter recipient Is a sample available for evaluation? Is a sample return box needed? Ship To address
Submission Details Submission Number Submission Date Incident Date Customer Ref. Number Notification Number Status	Product Information Product Line Product Code Lot Number Number of Incidents Instrument Serial Number Software Version Product Collected (ml) Donor Bleed Number	Problem Details When was the problem detected? Identify the problem type Problem Location

Enter ship to address here. If applicable.

Attached Files

Plasma Collection Assembly

RBC/Plasma Kit & Plasma Kit Satellite Plasma Containers Plasma Satellite Label



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

The screenshot shows the 'Product Performance for Disposables' submission page. At the top left is the Fresenius Kabi logo. At the top right are navigation links: 'Product Performance', 'Search', 'Account', 'Log Out', and 'Admin'. The main heading is 'Product Performance for Disposables' with a sub-heading 'Submit a Disposable Performance Report'. Below this, it says 'Select a Product Line to begin a Performance Report Submission:'. A table titled 'Medical Device Disposables:' lists various product lines in blue buttons: Agilia, Alyx®, Amicus®, Aurora Xi®, Autopheresis-C® or Aurora®, Solution Only, Bioflex®, Com.Tec®, INFusia, MNC, TPE, and Whole Blood. To the right of the table, there is a paragraph stating 'Fresenius Kabi takes quality seriously...' and an 'Important:' note about reactions or injuries. Below that are contact numbers for the US and Europe. At the bottom right, a grey box contains an email address for updates: mdcomplaintsupport@fresenius-kabi.com.

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, notification number, or donor bleed number

5. Once your parameters are entered click “Search”

The screenshot shows the 'Search Performance Report' form. The heading is 'Search Performance Report' with a sub-heading 'Use the form below to search for submitted product performance reports:'. The form is divided into two main sections: 'Choose an account:' and 'Search By Date:'. The 'Choose an account:' section has a dropdown menu labeled 'Select An Account'. The 'Search By Date:' section includes fields for 'From Incident Date:', 'To Incident Date:', 'Product Line:', 'Product Code:', and 'Lot Number:'. To the right, the 'Search By Identifier:' section has a heading 'Choose one of the options below:' and four radio button options: 'Submission Number', 'Customer Reference Number', 'Notification Number', and 'Donor Bleed Number'. A blue 'Search' button is located at the bottom right of the form.

Search Results

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

Search Results											
Submission #	Account #	Account Name	QA Contact	Product Line	Incident Date	Product Code	Product Description	Lot Number	Problem Detected	Problem Type	Status
60	60019464			Bioflex	03/01/2022	4B7891X	ACD-A IN 1000ML PLASTICCONTAINER	FM21L23422	Filtration	Illegible	Submitted
64	60039909			Amicus	03/01/2022	4B7898Q	ACD-A 500 ML (PACK FACTOR 24)	fa21f45342	Prime _____%	Other (Please Specify)	Submitted
65	60037587			Amicus	03/02/2022	4R2256	PLASMACELL-C DISPOSABLE SET	fa21f45342	Prime _____%	Particulate Matter	Submitted
67	60034710			Alyx	03/01/2022	4R2440	16G NEEDLE W/ PLASTIC MASTERGUARD	fa21f45342	Draw Cycle #	Restriction / No Flow	Submitted
69	60023365			Alyx	03/01/2022	FUM4092	4% ANTICOAGULANT SODIUM CITRATE,250ML	fa21f45342	Draw Cycle #	Restriction / No Flow	Submitted
70	60019431			Alyx	03/09/2022	X4R5720	ALYX 2RBC-LR KIT	fn21f45342	Set Up	Broken	Submitted

To start a new search, [click here](#)

[Export to Excel](#)

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

3. 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	M	N	O	P	Q	R	S	T
Submission #	Account #	Account Name	Status	Notification	Customer	QA Contact	Product Line	Adverse Event	Adverse Event	During Donation	Product Lot	Soft Good	Infusion Set	Incident Date	Drug Admin	Drug Used	Is Cytotoxic	Manufacture	
60	60019464		Submitted				Bioflex	No		No	Yes	Yes	Yes	3/1/2022					
64	60039909		Submitted				Amicus	No		No	Yes	Yes		3/1/2022	N/A				
65	60037587		Submitted				Amicus	No		No	Yes	Yes		3/2/2022	N/A				
67	60034710		Submitted				Alyx	No		No	Yes	Yes	Yes	3/1/2022					
69	60023365		Submitted				Alyx	No		No	No	No	No	3/1/2022					
70	60019431		Submitted				Alyx	No		No	No	No	No	3/9/2022					

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

Veeva document #0003-GEN-01-02/19

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