

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

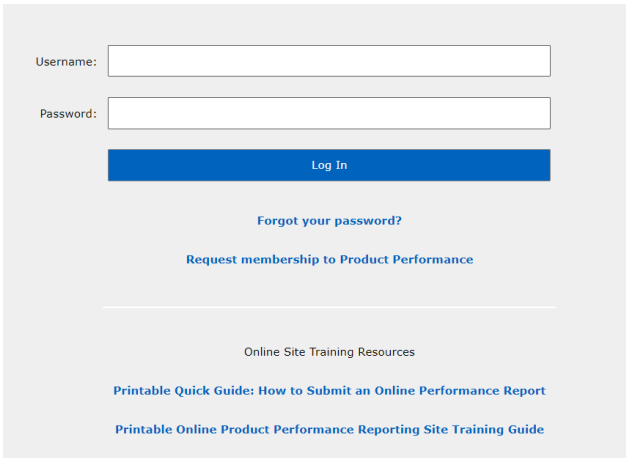
Step 1 – Go to the following link: <https://productperformance.FreseniusKabiUSA.com>

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

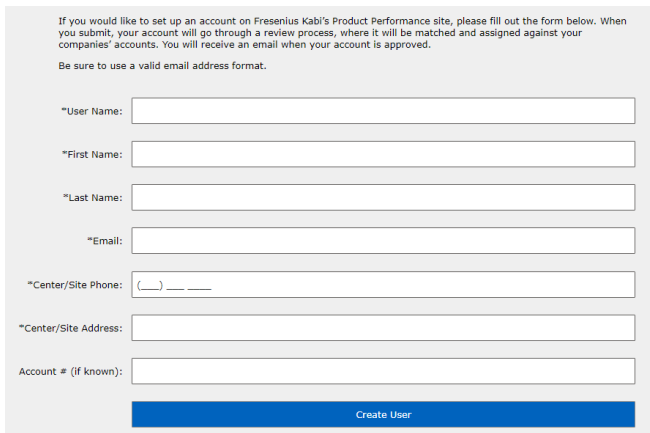
Step 4 – Receive email confirmation with username and password

Request Membership:



The screenshot shows a login and registration interface. At the top, there are two input fields: 'Username:' and 'Password:'. Below these is a blue 'Log In' button. Underneath the button is a link for 'Forgot your password?'. Further down is a link for 'Request membership to Product Performance'. At the bottom of the page, there is a section titled 'Online Site Training Resources' with two links: 'Printable Quick Guide: How to Submit an Online Performance Report' and 'Printable Online Product Performance Reporting Site Training Guide'.

Enrollment Screen:



The screenshot shows an enrollment form with the following text: '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.' The form contains several input fields: '*User Name:', '*First Name:', '*Last Name:', '*Email:', '*Center/Site Phone: (____) ____-____', '*Center/Site Address:', and 'Account # (if known):'. At the bottom of the form is a blue 'Create User' button.

Entering a Report: Account Information and General Incident Information

1. Select your Account Number (any field with an * is required for submission)
2. Complete the required General Incident Information. Add any additional information you choose to report.

If you click yes to report an adverse event, an additional field will populate. Complete the field with a description 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 performance report

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. Complete additional required and optional 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 problem 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

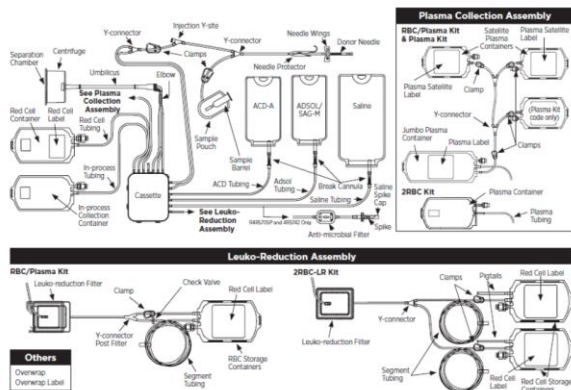
1. In the diagram below, click on the name of the area where the problem happened.

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 at the top of the diagram 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 in 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

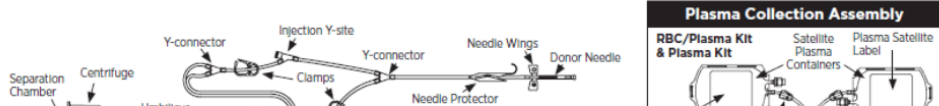
1. Click "Submit" to submit your report
2. The following screen will populate. The submission number can be found under the submission details

Alyx System Kit Performance Report

Submit a new form Print

Account Details Account Account Name Account Address QA Contact Submitted By Nissa Riemer Work Phone (847) 550 2865 Fax Email Nissa.riemer@fresenius-kabi.com	General Incident Information Did the issue occur during a donation? No Was there any adverse event or injury? No Was the procedure successfully completed? No Was the procedure stopped due to a soft goods incident? No Was the product lost? No	Product Return Details Email address for letter recipient No Is a sample available for evaluation? Yes Is a sample return box needed? No Ship To address Enter ship to address here. If applicable.
Submission Details Submission Number 70 Submission Date 03/09/2022 Incident Date 03/09/2022 Customer Ref. Number Notification Number Status Submitted	Product Information Product Line Alyx Product Code X4R5720 Lot Number fn21f45342 Number of Incidents 1 Instrument Serial Number Software Version Product Collected (ml) Donor Bleed Number	Problem Details When was the problem detected? Set Up Identify the problem type Broken Problem Location Sample Pouch


Attached Files



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** Account Log Out Admin

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®	Com. Tec®
INfusia	MNC
TPE	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
1.800.933.6925

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

If you need to update your location/account number, please email us at: mdcomplaintsupport@fresenius-kabi.com.

Please provide your username and the updates you require.

You can search by incident date or date range, product line, product code, lot number, submission number, your reference number, notification number, or donor bleed number.

2. Choose your account number,
3. Enter your search criterion.
4. Click search

Search Performance Report

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

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

Donor Bleed Number

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 Cytotox	Manufact		
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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