

# 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

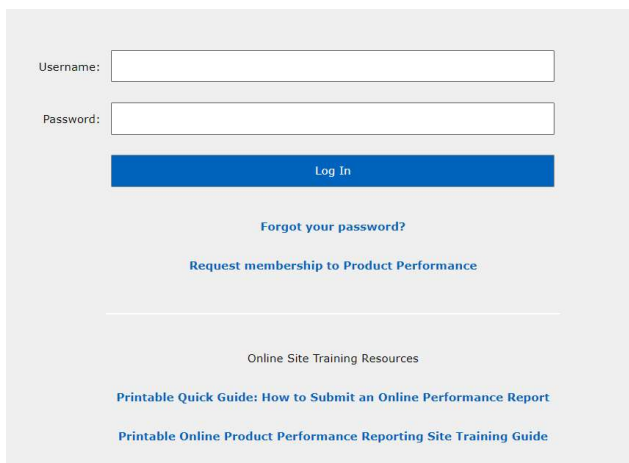
Step 1 – Go to the following link: <https://productperformance.FreseniusKabiUSA.com>

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:



Username:

Password:

[Log In](#)

[Forgot your password?](#)

[Request membership to Product Performance](#)

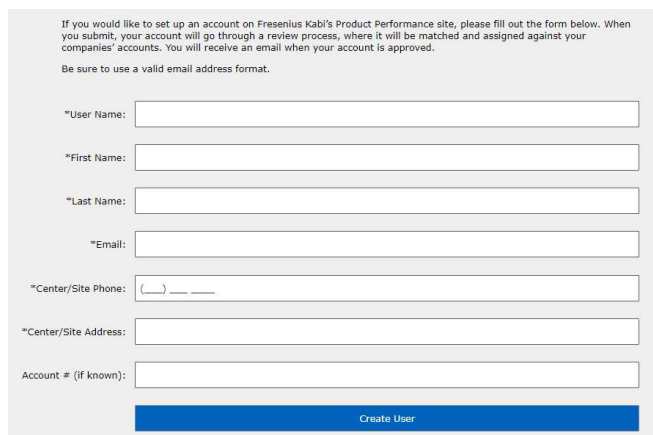
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Online Site Training Resources

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

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

## Enrollment Screen:



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:

\*Center/Site Phone: ( ) - -

\*Center/Site 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. 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:          | <input type="text"/>   |
| * Product Code:           | <div>No available products. Please select a suitable account</div> <div><a href="#">1</a> Add a Product Code</div> |
| * Lot Number:             | <input type="text"/>   |
| * Re-enter Lot Number:    | <input type="text"/>   |
| * Number of Incidents:    | <input type="text" value="1"/>   |
| Instrument Serial Number: | <input type="text"/>   |
| Software Version:         | <input type="text"/>   |
| Product Collected (ml):   | <input type="text"/>   |
| Donor Bleed Number:       | <input type="text"/>   |

## 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

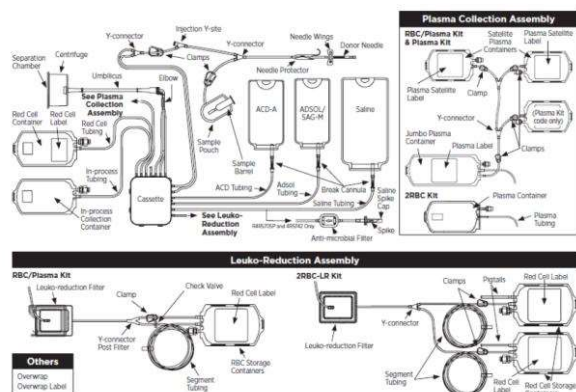
1. In the diagram below, click on the name of the area where the problem happened.

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](#)

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

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](mailto: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: 

Select An 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

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 PLASTIC CONTAINER      | 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    | FJM4092      | 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, <a href="#">click here</a> |           |              |            |              |               |              |  |            | 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 | Manufactured |   |   |
| 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](mailto: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.