Document Library: Electronic Delivery of Field Corrective Actions & Online Completion of Effectiveness Checks – Customer Overview and Training
In this Overview/Training you will…

- Gain an understanding of Document Library
- Have the ability to register for My Notifications
- Learn about the Customer Field Corrective Action Portal, including the FCA Registration option and functionality
What is Document Library?

Document Library is an electronic library for customers that provides a single point of access to the following customer documents:

- Instrument and software information
- Product quality documents
- Reagent and consumable information
- System application/Parameter sheets
- Technical/Reference documents
Did you know that Siemens Laboratory Diagnostics Document Library provides a single point-of-access to technical documents for our entire portfolio of instruments, assays, and test kits?

- The Document Library enables fast and easy, on-demand technical document retrieval.
- Registered customers can use search and refine, or simply browse documents by product line or document type.
- Customer access to the Document Library is available via restricted, authenticated, and password-protected log-in.

Access to the Document Library via the Siemens internet website is password protected, authenticated, and controlled.

http://www.siemens.com/document-library

Access requires registration:
- Name
- Email address
- Company name/address
- Sold-To
- Serial Number
- Product Name
Navigation: How to navigate through Document Library to find a document

1. Browse by:
   Product line, Product, and Document Type

2. Search by:
   Keyword

3. Filter by:
   Language, Lot number, country and date range
Navigation: You can browse by Product line, Product, and Document type

Browse by:
Product line, Product, and Document type
Navigation: General Search allows you to type in a Keyword

Search by Keyword: General
Navigation: Search by Reagent IFUs

Search by:
Reagent IFUs
File Management

File information [i]: allows a user to view information about the document.
Download files: users can download files and save to their computers for reference.

My Favorites: provides users with a place to store their most accessed documents.
Access: My Account – Document Library Profile will display Document Type, Product Lines and Products selected

All document types are defaulted to show all documents. However, you can de-select what you don’t want to show in Document Types.

Select all relevant product lines and products

Users will need to select:
Language
Country (Countries)
Receive email notifications for new and updated documents

The email notification feature provides alerts to registered users when documents are added and/or updated as well as when documents are retired from the Document Library.

Benefits:

- Automated notification alerts sent directly to your email account when documents are added, updated, or removed
- Easy access to new and/or updated documents
- Customizable notifications according to your profile selections (document type or product/products)

The email notification provides a listing of updated documents with links for accessibility via the Document Library login page.
Access: My Notifications can be configured to receive email notifications

My Notifications:
You can configure your preferences (Subscription Status, Frequency of Notifications and Organizational Preferences)
Access: Once selected, you will receive emails accordingly that show documents Added, Updated or Deleted/Removed from Document Library

My Notifications:  
Notification Email will be according to your preferences

This email shows:
- Added Documents (shows documents with links)
- Updated Documents (shows documents with links)
- Removed Documents (shows listing)
Customer Support

Access requires registration:
Name, Email address, Company name/address, Sold-To/Ship-To
http://www.siemens.com/document-library

Self-Service Help
Help button (top-right)
diagnostics-lab-docs.healthcare@siemens.com
Visit http://www.siemens.com/document-library

Register today and upon approval, receive access to Siemens technical documents.
Customer Field Corrective Action (FCA) Portal
The new capability within Document library allows you to receive Field Corrective Action (FCA) notices automatically via email and respond to Effectiveness Checks electronically.

**Benefits:**

- Faster delivery of FCA Letters to all registered users within your organization
- Immediate availability of FCA Letters via the Document Library
- Easier, faster completion and submission of Effectiveness Check forms online
Registration for Field Corrective Action Notification provides electronic delivery of FCA Letters and online completion for Effectiveness Checks

FCA Notification: Registration is optional

1. Select “Yes” to register.
2. Select the FCA User Type:
   - Primary User
   - General User
3. FCA Delivery Type is defaulted to Electronic, however, an option to receive paper notifications is available.
4. Select the Timezone for notifications.
5. Select the ship-to account(s) you are responsible for.
Customers can register for Field Corrective Action letters either as a “Primary” or a “General” user type

<table>
<thead>
<tr>
<th>Primary</th>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receives FCA Letters</td>
<td>Receives FCA Letters</td>
</tr>
<tr>
<td>Reviews Field Corrective Action Letters</td>
<td>Reviews Field Corrective Action Letters</td>
</tr>
<tr>
<td>Selects the link in email and takes action to complete the Effectiveness Check Response Form</td>
<td></td>
</tr>
<tr>
<td>Manages the set of Primary and General users for his Sold-To Location</td>
<td></td>
</tr>
<tr>
<td>Assigns delegates as needed</td>
<td>May be assigned as a “delegate” to complete the Effectiveness Check Response Form</td>
</tr>
</tbody>
</table>
Once registered for FCAs, customers can receive Field Corrective Action Letters through email

Receiving/Viewing FCA Letter delivered by email

Email Message contains two links:

1. Field Corrective Action letter in Document Library
   - Click on the Field Corrective Action letter link to open the actual referenced document (login to Document Library required).

2. Effectiveness Check Response Form
   - Click on the Effectiveness Check Response Form link to go directly to the Effectiveness Check Response Form to be filled out (login to Document Library required).

Field Corrective Action Notice

Dear Mr. John Smith,

Siemens has identified an issue and our records show that your facility has received this product(s).

1) Please click on Field Action Field Corrective Action Document to view and follow the instructions as indicated.

2) If you have responsibility for completing effectiveness checks for your facility, please click on Field Correction Effectiveness Check form, and complete and submit within 30 days.

We apologize for the inconvenience. Please be assured that product quality remains our number one priority. If you have any questions, please refer to the contact information provided in the Field Action.

IMPORTANT NOTE: It is essential that the Field Corrective Effectiveness Check form be completed and submitted by June 30, 2016.

If this communication should not have been directed to you, please update your Quality Communications profile in Laboratory Diagnostics Document Library.
Clicking on the Effectiveness Check Response Form link will go directly to the Effectiveness Check Response Form to be filled out

Effectiveness Check Response Form

Options for User:

- Fill out the form completely, save and submit
- Fill out the form and save for further updates
- Select either Partial or Completed
  - If Partial is selected, the information provided is for only a part of the site
  - If Completed is selected, the information is for the entire site
Customers can electronically access their Field Corrective Action Letters in a variety of ways

Access to Field Corrective Actions Letters through:

1. Email with links to FCA Letter and Effectiveness Check Form
2. Customer Field Corrective Action Portal in Document Library for “Primary Users”
3. Field Corrective Action Tab in the Document Library
Customer Field Corrective Action Portal Menu Screen in Document Library

Customer Field Corrective Action Portal Menu Screen (for Primary Users)

- View/update user registration profile
- View/manage Quality Customer Communications
- Administer all users for customer locations
- View/manage delegations
Customer FCA Portal: Registration (User Profile)

Select Registration (User Profile)
- Displays the User Profile
- Make updates in profile for Document Library and FCA Registration section and select Save Profile.
Selecting All FCA

- Displays the list of all FCA letters distributed for any Ship-to location for which the user is registered
- Shows the “Customer Status” of what has been completed or not submitted
- Select the “Effectiveness Check Response Form” and the form opens
- Select “Document” and the FCA Letter opens
### User Administration

- **List of the users**
- **List can be downloaded to one of the following formats:**
  - Comma separated file (CSV)
  - Excel spreadsheet
  - XML format file
- **Click on the specific user’s email address, and the profile is displayed**
**Customer FCA Portal: User Administration**

**Changing a User Profile**

Fields in shown boxes can be changed

Select Status:
- **Active**: User has access to Document Library and FCA letters
- **Inactive**: User **cannot** access Document Library and FCA letters

Select Field Correct Action User Type
- Primary User or General User

Select Field Corrective Action Delivery Type
- Electronic or Paper

Select Timezone (from the list)

Click on the box for Ship-to accounts for which the user is responsible for

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**Requirement for at least one Primary in each Customer Account**

- During administration, if the user attempts to change everyone to a “General” user, resulting in no “Primary” users for the SoldTo location, an error is raised and the change cannot be made.
Customer FCA Portal: Delegations

**Customer Delegation Overview**

Delegations can be assigned if someone is planning to be out of the office or on vacation for a period of time.

Assign a delegation

List of users for the SoldTo Customer who are eligible to be assigned as delegates

Please click on a user in the table to assign a new delegation.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>User Email</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>James</td>
<td>Mason</td>
<td><a href="mailto:james.mason@stvincents.com">james.mason@stvincents.com</a></td>
<td>St. Vincent's Medical</td>
</tr>
<tr>
<td>Carol</td>
<td>Bruno</td>
<td><a href="mailto:cbruno@acmehospital.com">cbruno@acmehospital.com</a></td>
<td>Acme Hospital Network</td>
</tr>
</tbody>
</table>

**Current delegations**

List of currently assigned delegations

Please click on an entry in the table below to edit or cancel the delegation.

<table>
<thead>
<tr>
<th>Customer Name</th>
<th>User Number</th>
<th>User Email</th>
<th>Delegation Start Date</th>
<th>Delegation End Date</th>
<th>Modification User Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Vincent's Medical</td>
<td>10440</td>
<td><a href="mailto:james.mason@stvincents.com">james.mason@stvincents.com</a></td>
<td>5-06-23</td>
<td>2015-09-30</td>
<td><a href="mailto:hurricat4450@gmail.com">hurricat4450@gmail.com</a></td>
</tr>
</tbody>
</table>

**Delegations**

- Only visible to users with role of “Primary”
- Shows a list of all “General” users for the Customer Locations who are eligible to be assigned as a delegate
- Delegations can be assigned and cancelled by any “Primary” user
- Delegation is automatically cancelled after the designated “Delegation End Date”
Customer FCA Portal: Delegations

To Assign a Delegation

1. Click on a User in the table
2. Select the user for delegation
3. Select Start Date
4. Select End Date
5. Click Save and Delegation is set
In Summary

Document Library is an electronic library for customers that provides a single point of access to the following customer documents:

- Instrument and software information
- Product quality documents
- Reagent and consumable information
- System application/Parameter sheets
- Technical/Reference documents

Field Corrective Action Notification registration provides electronic delivery of FCA Letters and online completion for Effectiveness Checks.
If you would like to register to receive Field Corrective Action Letters via email, and respond electronically to Effectiveness Checks, please register for Document Library / Field Corrective Action Letters at:

http://www.siemens.com/document-library-registration

If you are already a registered Document Library customer, please go to your user profile in Document Library and select FCA Registration and follow the prompts.