Agilent
Cross**Lab**
From Insight to Outcome

Smart Alerts Chromatography Data System (CDS) Compatibility Statement

Introduction

The intent of this paper is to communicate Agilent Technologies' position regarding the deployment of Smart Alerts on CDS standalone workstations, acquisition controllers and client/server computers in GxP regulated environments.

This white paper is intended to help users of Smart Alerts whose organizations must comply with regulatory requirements.

Agilent Smart Alerts

Smart Alerts is an on-premises application set of services with a web-based front end. Users access the Smart Alerts user interface with a web browser from the same or other networked PC. Smart Alerts is an end-user installable software application that runs on any PC internal to the customers' laboratory without the need for an Internet connection.

Smart Alerts is a notification tool used for planning and optimizing instrument management, usage, and capacity. The application monitors Early Maintenance Feedback (EMF) and usage data, such as pump seal wear, from instruments across the laboratory, against application-specific insights provided by Agilent. It can also be customized to specific requirements. It delivers notifications/alerts to users about preventive maintenance (PM) status, whether an instrument is in a fault state, or when to change key consumables.

Smart Alerts is designed to help customers be more productive and efficient by providing timely, usage-based recommendations for laboratory system maintenance and system fault alerts. This software enables an increased system uptime and ensures sustained instrument performance, particularly for high-use instruments in high throughput laboratories.

Smart Alerts does not modify, manipulate, influence, or impact any analytical data generated by the CDS. It operates independently of the CDS and communicates directly with the instrument. It does not change any instrument settings. For instruments isolated from the laboratory, network communication can also be achieved via the Smart Alerts Relay Service software.

Agilent

Smart Alerts is a non-invasive software application designed to run in both a standalone workstation and client/server environments. It makes no changes to the native CDS files.

1
Install Smart Alerts on any PC in your lab in 10 minutes or less. No Internet connection is required.

2
The software compares instrument-use data against application-based insights from Agilent. (customizable)

3
Receive an email when recommended limits are reached.

Compatibility Testing: Test Plan/Scope

Smart Alerts is sometimes installed on CDS PCs for evaluation purposes.

The Agilent Relay Service is installed on CDS PCs for Smart Alerts to communicate to Agilent systems connected to the CDS.

To ensure the co-residence of Smart Alerts and native CDS acquisition software would not negatively impact either a software application, CDS compatibility and instrument performance testing was completed using Smart Alerts A.01.05/HF1 installed in the following CDS configurations:

Table 1. Agilent OpenLab

OpenLab Installation Type	CDS Revision	PC Type	Agilent Component	Tested Hardware Configuration Tested
Workstation	Workstation	Workstation	Smart Alerts	LC, GC, and SQ GCMS
	Workstation Plus	Workstation	Smart Alerts	LC, GC, and SQ GCMS
Client/Server	Client-Server	Client	Smart Alerts	LC, GC, and SQ GCMS
		Server	Smart Alerts	LC, GC, and SQ GCMS
		AIC	Smart Alerts	LC, GC, and SQ GCMS
	Client-Server With ECM XT	Client	Smart Alerts	LC, GC, and SQ GCMS
		Server	Smart Alerts	LC, GC, and SQ GCMS
		AIC	Smart Alerts	LC, GC, and SQ GCMS

Table 2. Agilent OpenLab CDS Chemstation Edition

OpenLab CDS Chemstation Installation Type	CDS Revision	PC Type	Agilent Component	Tested Hardware Configuration Tested
Workstation	Workstation ECM XT	Workstation	Smart Alerts	LC, GC and GC/MDS
	Workstation ECM XT (with Content Manager)	Workstation	Smart Alerts	LC, GC and GC/MDS
Client/Server	Client Server ECM XT	Client	Smart Alerts	LC, GC and GC/MDS
		AIC	Smart Alerts	LC, GC and GC/MDS

Table 3. Waters™ Empower™ Version 3 - with Smart Alerts A.01.05 / HF1*

Agilent Component	Waters™ Installation Type	CDS Revision	PC Type	Tested Hardware Configuration Tested
Smart Alerts	Empower™ Personal	Feature Release 4	Workstation	LC and GC
		Feature Release 5	Workstation	LC and GC
Smart Alerts	Empower™ Enterprises	Feature Release 4	Client	LC and GC
		Feature Release 5	Client	LC and GC
Agilent Relay Service	LAC/E™	Feature Release 5	LAC/E™	LC and GC

For software compatibility testing, the following test plan/scope was followed (for OpenLab CDS):

- **Perform Software OQ (file validation):** Install CDS on PC. Run software Operational Qualification via Agilent ACE (Automated Compliance Engine). Verify all tests pass

- **Evaluate Smart Alerts performance:** Smart Alerts can function as expected (connect and monitor instruments, edit/ delete instruments, receive notifications for both maintenance and faults, and receive Smart Alerts upgrades)

- Monitor memory consumption of all Smart Alerts-enabled services

- Testing completed on supported PC Operating System (OS) configurations

- **Evaluation of instrument/CDS performance by confirming:**

    - Communication with the instrument and

    - Successful execution of:

        - An injection (for LC/GC)

        - An autotune (for GCMS)

For instrument performance testing a representative model/stack for each supported configuration was chosen:

- Agilent LC (1260 or 1290 Infinity or Infinity II)

- Agilent GC (7890, 8860, 8890, 9000)

- Agilent single quadrupole GCMS (597x series)

A modified test plan/scope was followed for Agilent OpenLab CDS Chemstation Edition and Waters™ Empower™.

Compatibility Testing: Test Results

The test plan execution verified that the installation and operation of Smart Alerts and its Relay Service software component did not impact the operation of the CDSs listed above.

Smart Alerts validation documentation can be made available to Agilent customers through the completion of an Agilent standardized Confidentiality Disclosure Agreement (CDA) process. Submission of a signed CDA for the Smart Alerts to be installed would result in Agilent providing data associated with the validation life cycle. It should be noted that the content of this data is drawn directly from existing Agilent validation life-cycle documentation.

Co-residence testing of Smart Alerts A.01.05 HF1* was successfully completed with OpenLab 2.4. It can be concluded that newer revisions of OpenLab and Smart Alerts should not be negatively impacted.

* Standard installation with no additional add-on software.
Refer to Agilent Smart Alerts A.01.05 Compatibility Matrix for more information on supported hardware configurations.

Risk Assessment

The Agilent Smart Alerts software platform is designed, developed, and validated by the developer (Agilent Technologies, Inc.) and follows the approved validation life-cycle process within the Agilent ISO Accredited Quality Management System. Validation certificates for the Smart Alerts software are generated automatically as part of the life-cycle process, prior to software release, and are available on request. The certificate includes a declaration of intent statement and is a representation of the life-cycle process followed, with high-level details of the key stages listed below:

Declaration of Product Validation

Agilent Technologies

Declaration of *CrossLab Smart Alerts* Validation

We herewith inform you that the:

CrossLab Smart Alerts
Product Name

Software version A.01.05
Revision Number

was developed and tested according to the Agilent Technologies Chemical Analysis Group Lifecycle. Lifecycle checkpoint deliverables were reviewed and approved by management. The product was found to meet its functional and performance specifications, and release criteria at release to shipment.

In order to support the user's requirements for certification of this product under 21 CFR 58 (Good Laboratory Practice), 21 CFR 210 (Good Manufacturing Practice for Drugs), or 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals), we will make the following documents available to an authorized governmental or regulatory agency for inspection at Agilent Technologies/ACG, Santa Clara, California, USA.

Product Description
Lifecycle Phase Checkpoint Approval Documents
Test Documentation
Defect Documentation
Design Documentation
Revision Status

Agilent Technologies will maintain possession of all documents and their reproductions and may require a non-disclosure agreement to be provided by those requiring access to these documents.

Neil Cook
Agilent CrossLab Group R&D VP and Dir. Of Technology

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Agilent CrossLab Group Quality Manager

17 January 2020
Date

- ☑ Product Description / Specification
- ☑ Life-cycle Phases / Transition Approvals
- ☑ Quality Assurance / Testing
- ☑ Documentation and Change Management
- ☑ Source Code

Conclusions

Smart Alerts integrate into the laboratory infrastructure and adapt easily to procedural controls, documented in site quality Standard Operating Procedures, supporting a wide variety of use cases.

Smart Alerts software is designed to be independent of the CDS. No chromatography data, generated by the CDS is impacted, modified, or manipulated by the Smart Alerts software.

Smart Alerts integrates into the laboratory infrastructure and can adapt easily to procedural controls documented in site quality Standard Operating Procedures, supporting a wide variety of use cases. It provides an independent and validated assessment of laboratory equipment status that is harmonized across multiple techniques, with alert notifications that are designed to be easier to review by an end-user.

Access to Smart Alerts requires user login and password configured within the Smart Alerts application.

As Smart Alerts is not involved in producing analytical data, a software qualification is not required.

The validation life cycle followed by Agilent for Smart Alerts and its Relay Service software component ensures that the installation of Smart Alerts on a customers' workstation/instrument network does not impact:

- the qualification status of the instrument
- the validation status of the CDS or the PC, A/C or Waters™ LAC/E™ box on which it resides

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Frequently Asked Questions (FAQ)

My lab has no Internet! don't Smart Alerts require the customer's lab to have an Internet connection?

Actually no. Smart Alerts is designed to run completely on-premises, without Internet, cloud or through-the-firewall connection required.

But isn't an Internet connection required for the customer to use Smart Alerts' email capabilities?

Not necessarily. Many companies have internal SMTP email servers for applications like Smart Alerts. Their firewall settings are different for email vs. Internet usage. You should consult with your IT organization on this. It can be surprisingly easy to set up once they have the required settings.

Can Smart Alerts be installed on a CDS workstation?

Yes. This is in fact how most installations are configured today. This will work fine for a few connected instruments, e.g. 3-4. For the best performance, we recommend moving it to a separate PC when the customer is ready to add more systems beyond this.

Will my IT organization block the use of Smart Alerts? What's IT's involvement?

The answer is entirely dependent on the company's IT policies. We have had very few objections from IT, particularly since Smart Alerts doesn't use the Internet. The application is small and easy to set up. Some companies only allow IT to install the software. In these cases, a good approach is to provide your IT department with the technical documentation on Smart Alerts available from your Agilent Support Engineer or Account Manager. We expect this will be enough for them to agree to move forward in most cases.

Can Smart Alerts be configured/customized?

Yes, Smart Alerts can be configured to create EMF templates that satisfy customer requirements.

Will Smart Alerts work in a non-Agilent CDS environment, e.g. Waters™ Empower™?

Yes. Because Smart Alerts collects its information directly from instruments, there is no CDS connection needed. It runs completely independent of the CDS.

How will I know when the new features are available?

Several ways:
1) You will receive an email from SubscribeNet whenever a new release is available;
2) We will be communicating new features using a tool called Constant Contact. You always have access to the latest version. Smart Alerts can be updated in place in just a few minutes without any loss of data or instrument connections;
3) If you are connected to the internet, you will automatically receive notifications of new features and builds directly from the User Interface itself.

Will Smart Alerts stop running when my subscription expires?

Smart Alerts will turn itself off one year after installation. It will give the end-user several communications before doing this. At that time you will have to renew your subscription and download the latest version to continue using Smart Alerts. No data will be lost in this process.

This sounds like "free-of-charge."

Smart Alerts is not freeware. It has a subscription price of $120 per connected instrument per year. Customers can get it on a free trial use basis with one of our promotions.

Even though the software is free, doesn't it still require a lot of effort to set up Smart Alerts?

No. Smart Alerts was designed to be customer-installable on any PC in the lab. It installs like any other PC app, and the process can be completed in 10-15 minutes.

How well does Smart Alerts work in a client-server environment?

Smart Alerts works especially well in client-server environments. Again, it doesn't interfere with the CDS system. Smart Alerts is a server-based application itself. Because in these configurations the instruments are frequently connected directly to the laboratory network, connecting Smart Alerts to the instruments is especially straightforward. You simply enter the instrument IP addresses.

Will Smart Alerts effect validated laboratory environments?

Smart Alerts operates independently of the CDS, it does not modify, manipulate, influence, or impact any analytical data generated by the CDS. Customers who installed Smart Alerts, in validated environments, confirm that revalidation of the CDS was not necessary in accordance with their compliance SOP.

Is Smart Alerts Validated?

Yes, Smart Alerts software and its Relay Service component are managed under change control and follow an approved validation life cycle within Agilent's global ISO Accredited Quality Management System.

References

1. Agilent Smart Alerts A.01.05 Current Product Engineer (CPE) Plan.
2. Agilent Smart Alerts A.01.05 Validation Certificate.
3. Agilent Smart Alerts A.01.05 Compatibility Matrix.
4. Agilent TCP Relay Service - Administrators Guide.

Contact Agilent

To find out more about Agilent products, services and consultancy capabilities, and how they can help you achieve your laboratory goals, contact your local Agilent representative.

www.agilent.com/chem/crosslab-smart-alerts

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