

Operator user guide

Field Data Manager

This guide is intended for QC and/or operations to review and annotate records. Further instructions for administrators for set up and preferences can be found in [BA00288R/09/EN/12.21](#).

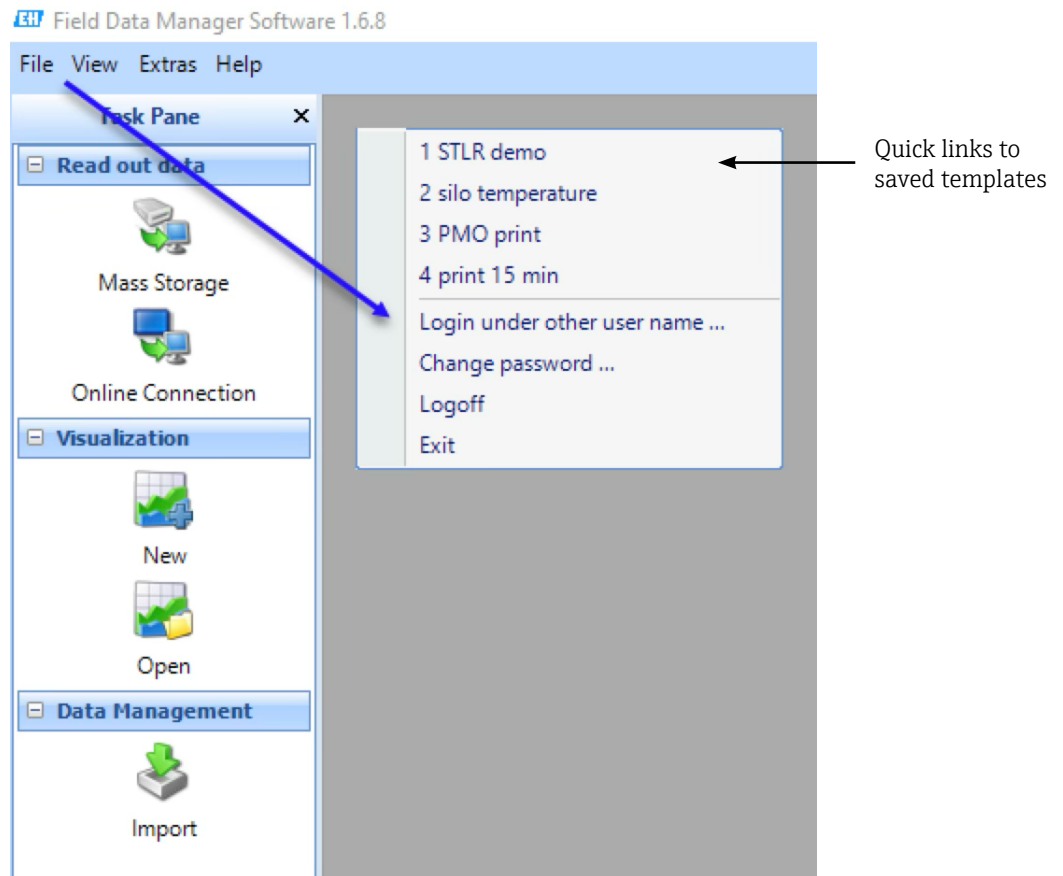


Field Data Manager (FDM)

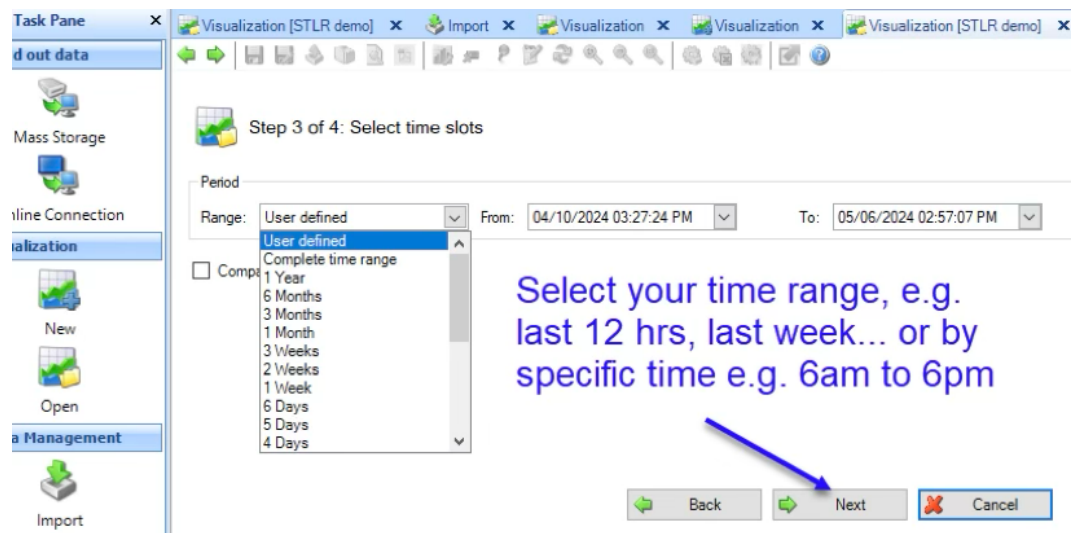
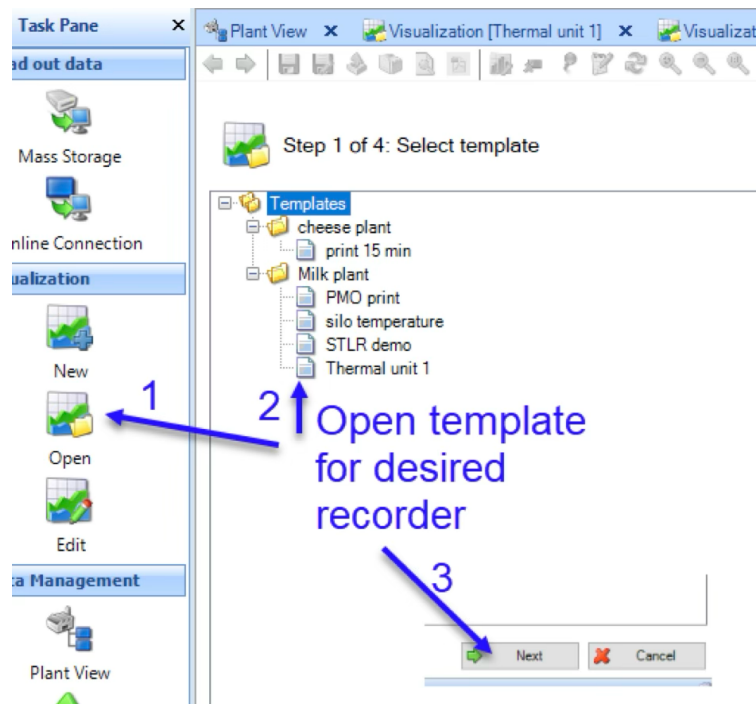
- Reporting software for data management and visualization
- Used in connection with Memograph M RSG45 to ensure compliance with 21CFR, part 11 (electronic records, signatures)
- Used for review of records and electronic signatures as proof of review
- Electronic signature/entries is by means of identifiable username and personal password
- Automatic transfer via ethernet connection is set up by administrator/IT
- Templates and naming for each recorder is set up by administrator
- Usernames can only be created/changed/deleted by administrator

Field Data Manager (FDM) login

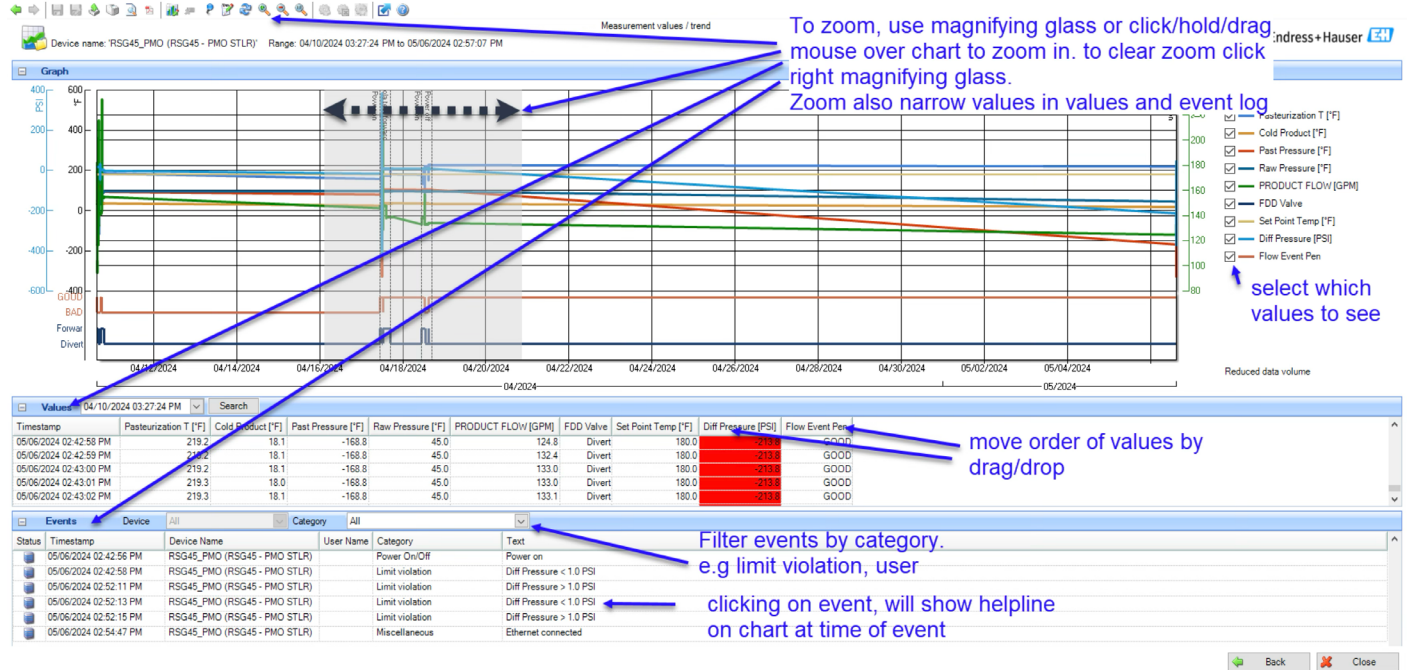
FDM MS21 (server version) allows up to five concurrent users to be logged in simultaneously. We recommend auto logoff after five minutes to be set up by the administrator.



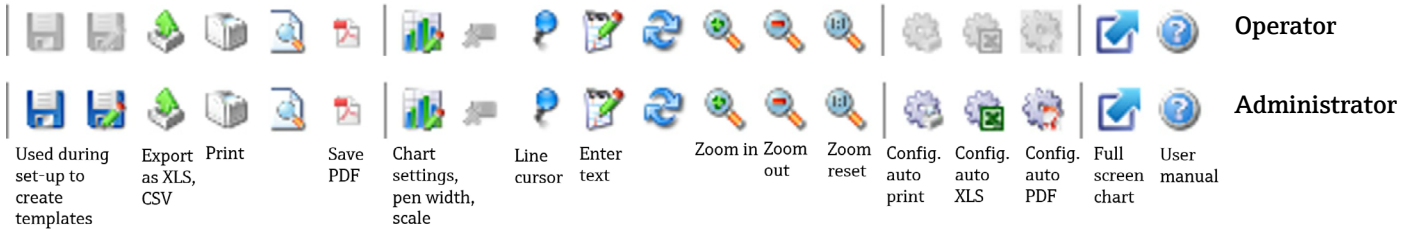
Select which recorder and timeframe to view



User screen – most used function

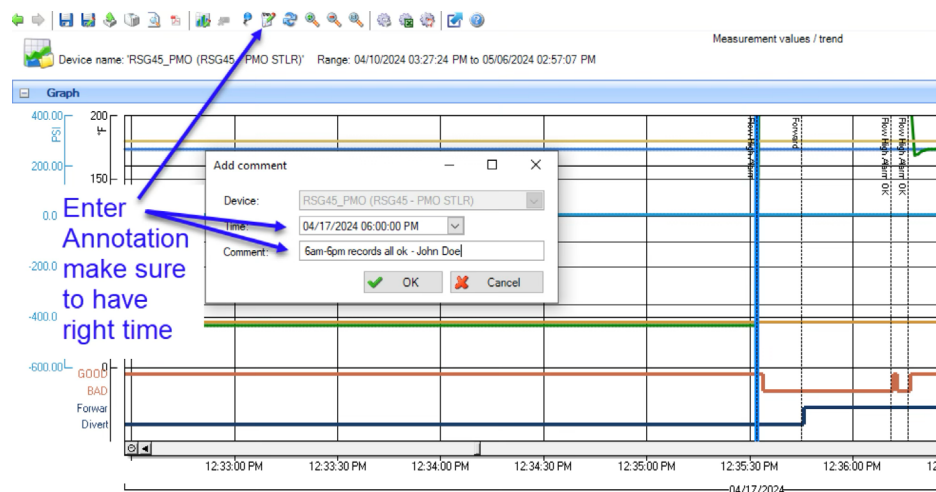


Menu bar



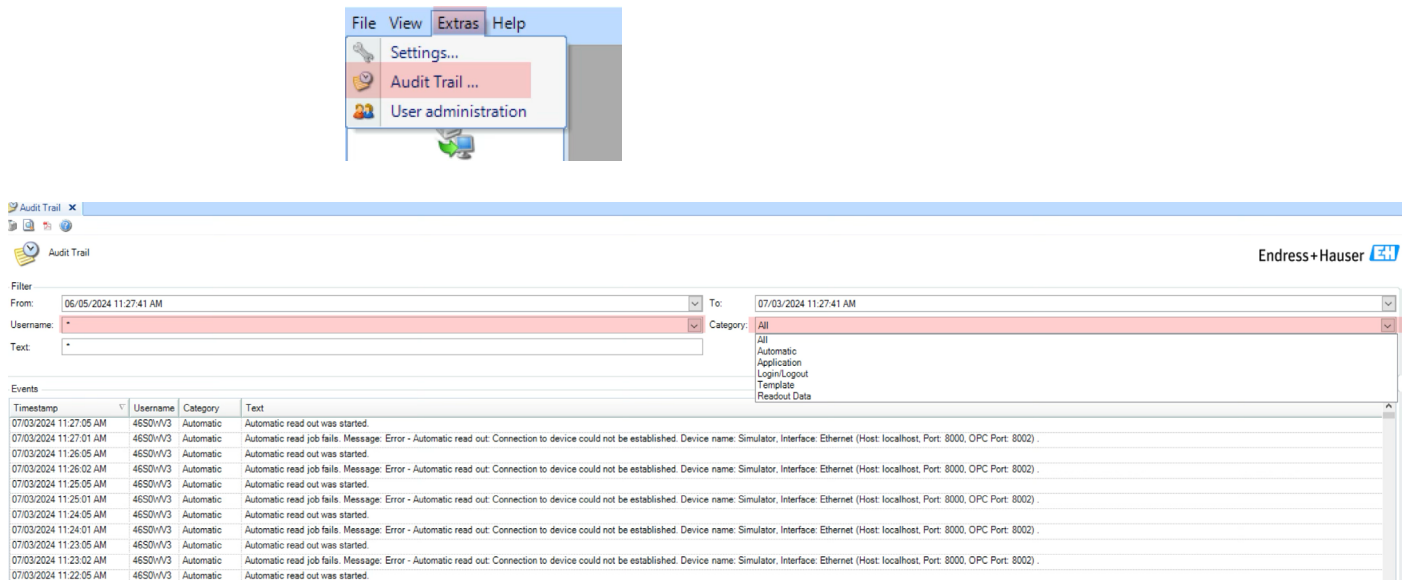
Add annotation – sign off

- Annotations can be made at any time to highlight events, etc.
- Also used to sign off on charts, e.g., every 12 hours or per local SOP
- Example: reviewed data 6 a.m.– 6 p.m.
- Up to 42 characters
- Entries cannot be deleted (another entry can be entered at same time for correction)



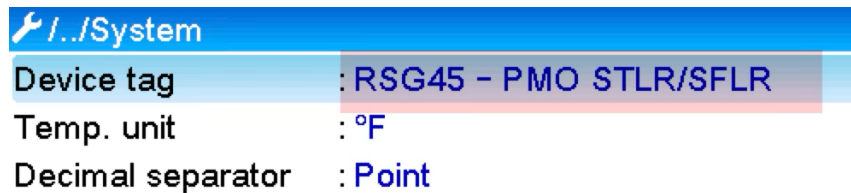
Audit trail

- Search any event in the audit trail
- Filter by individual or event category



For administrators, FDM MS21 server setup

Before starting, make sure Memograph M RSG45(s) is connected and named with a unique device tag for easy identification. This becomes more critical as several Memograph M RSG45s are added.

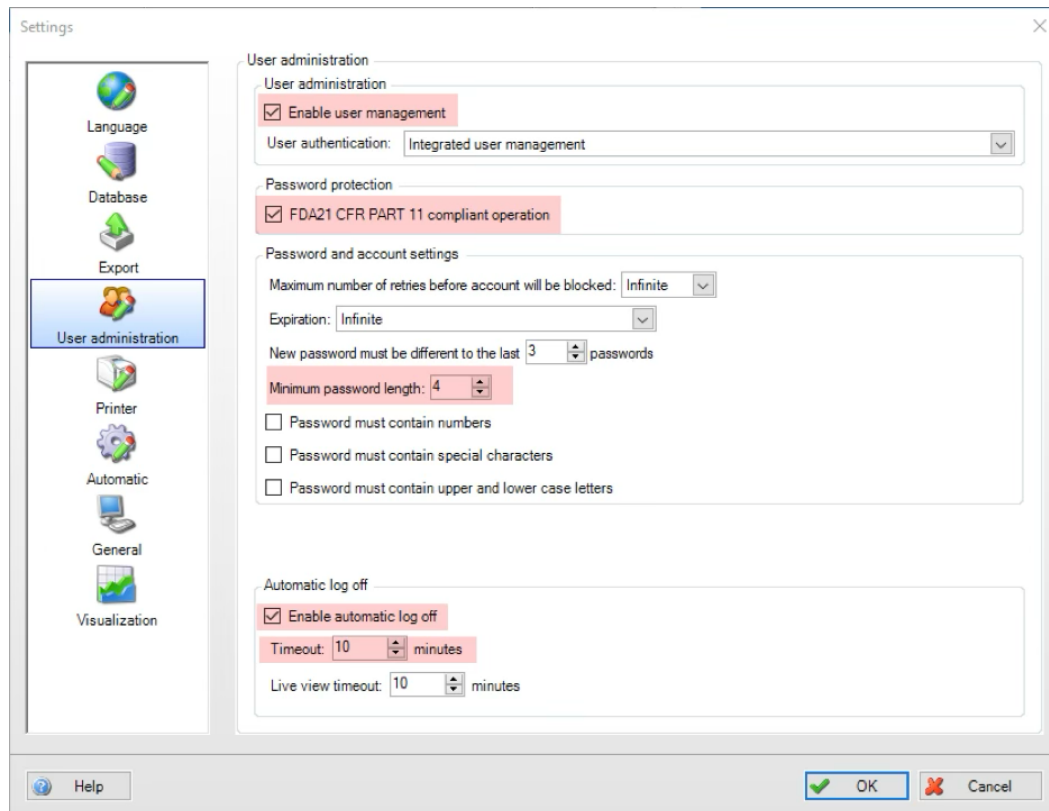
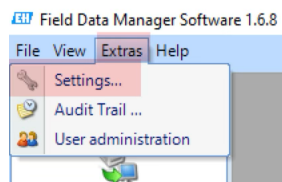


Note for administrator: Each recorder must have a unique tag identifier (device name). This is set in Memograph M RSG45 (menu, setup, advanced setup, system).

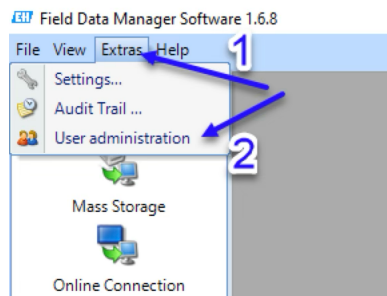
For server or PC setup and connection, [click here](#). Go to page 27 for English.

For administrator – add/delete operators

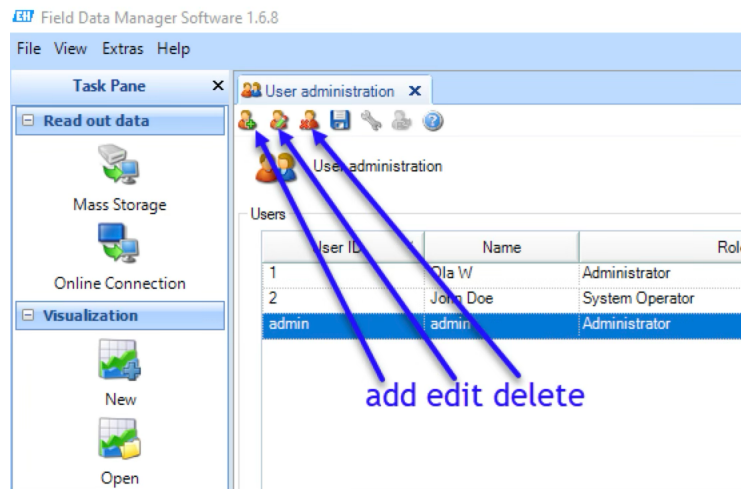
1. Set password rules, auto logoff and preferences under extras-settings-user admin; FDA21CFR, part 11 must be enabled



2. Create, edit, delete users



3. Must be logged on as administrator
 - a. User ID is alphanumeric up to 8 characters, e.g., individual name, initials, employee number or another unique identifier. User ID is what will show on the login screen. Both user ID and real name will show in the event log
 - b. Select System Operator to enable annotations



Operator access restrictions

- Admin has access to all recorders connected to FDM
- System operator can be limited to view recorders only relevant to job function
- Go to extras – user administration. Select operator, then checkmark relevant recorders for access

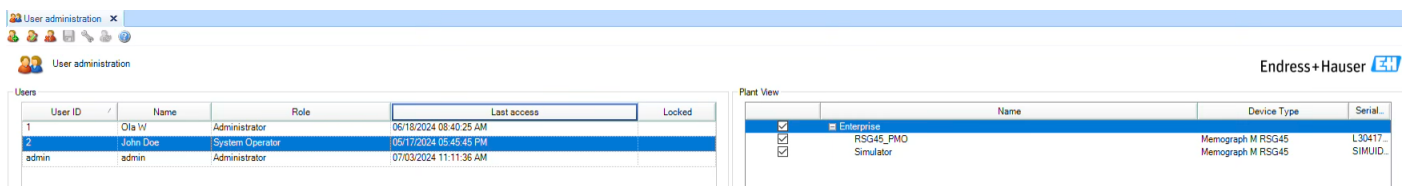
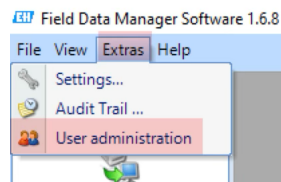
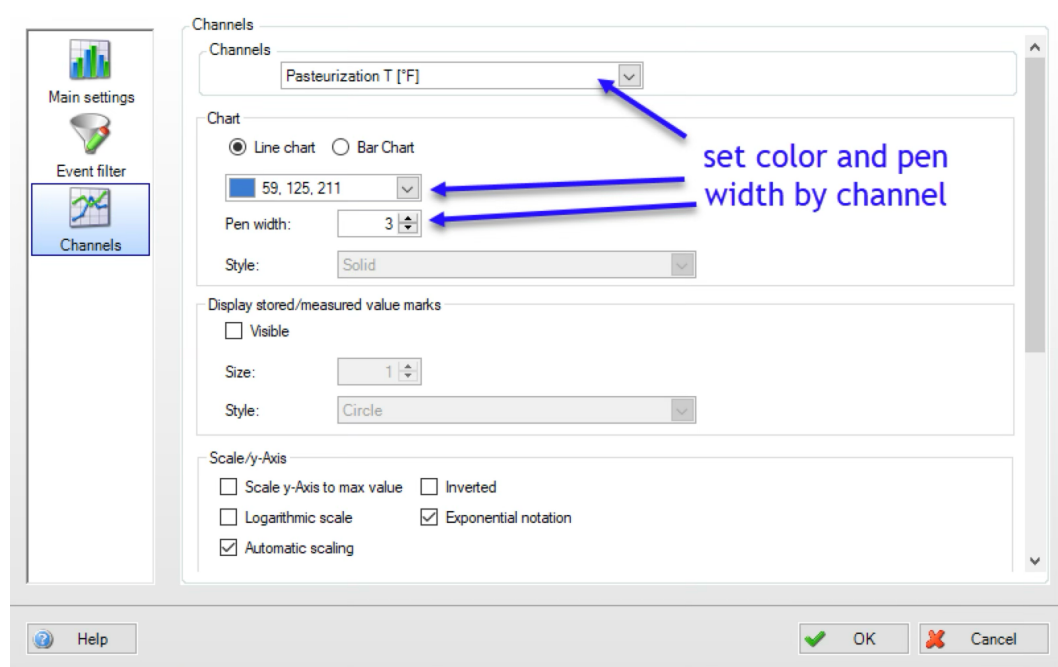
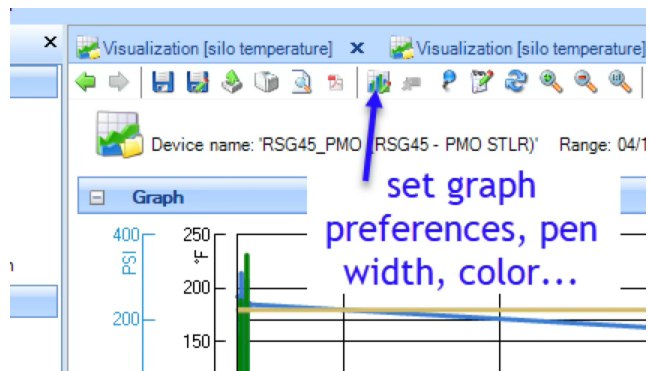


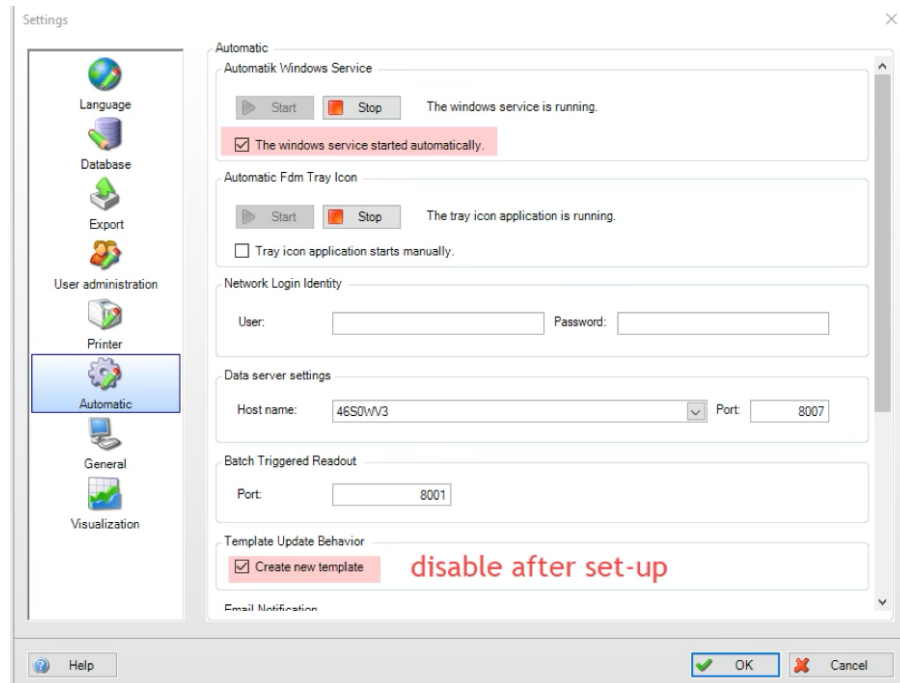
Chart preferences

- Save as template
- While preferences can be changed at any time, it is suggested to set up once and then use “template function” to recall data under preferred templates (The user can choose from multiple templates.)



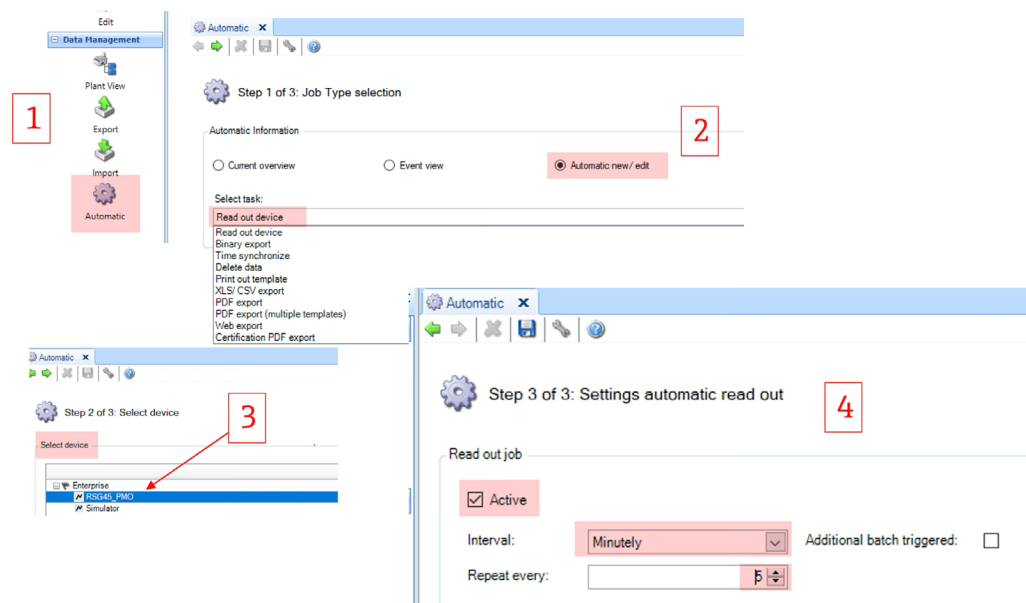
Automatic functions – preferences

- The Windows service starts automatically
- We suggest disabling “create new template” after initial setup.
If not, it will ask each time when exiting



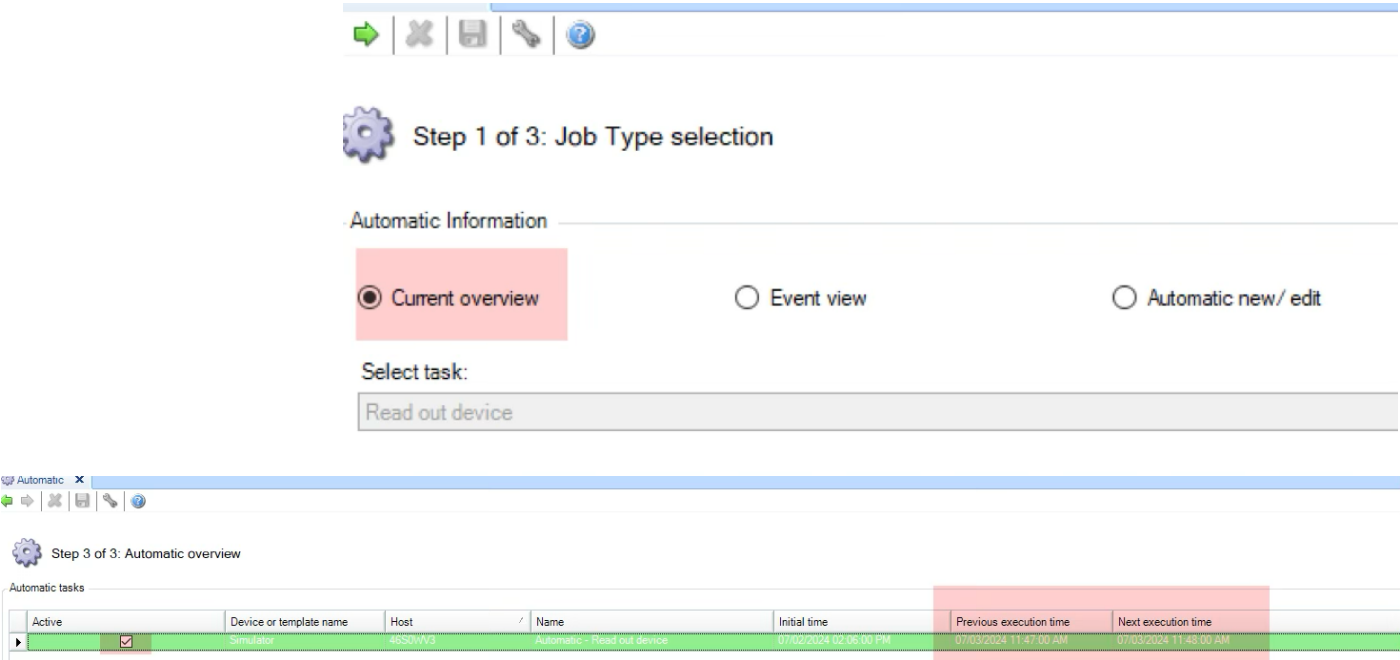
Set up automatic read out (store data from recorder to FDM/server)

1. Go to automatic
2. Select new/edit (read out device)
3. Select recorder(unit)
4. Set frequency; we suggest every 5 minutes to reduce the risk in the event of catastrophic failure of the recorder



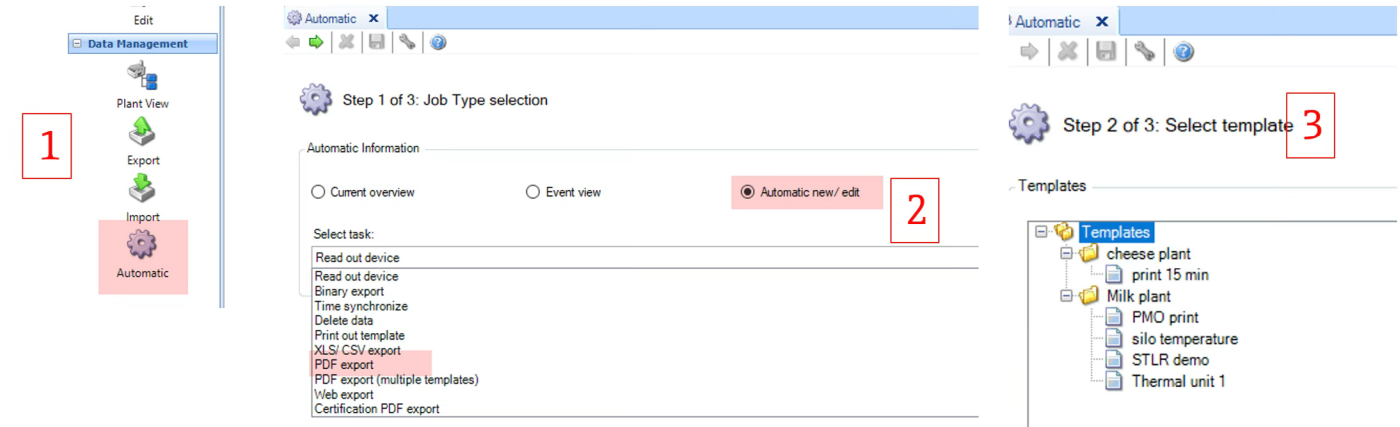
Verify that automatic transfer takes place

At any time, check which schedule automatic transfer is set to and see next occurrence.



Automatic creation of PDF / other exports* (1)

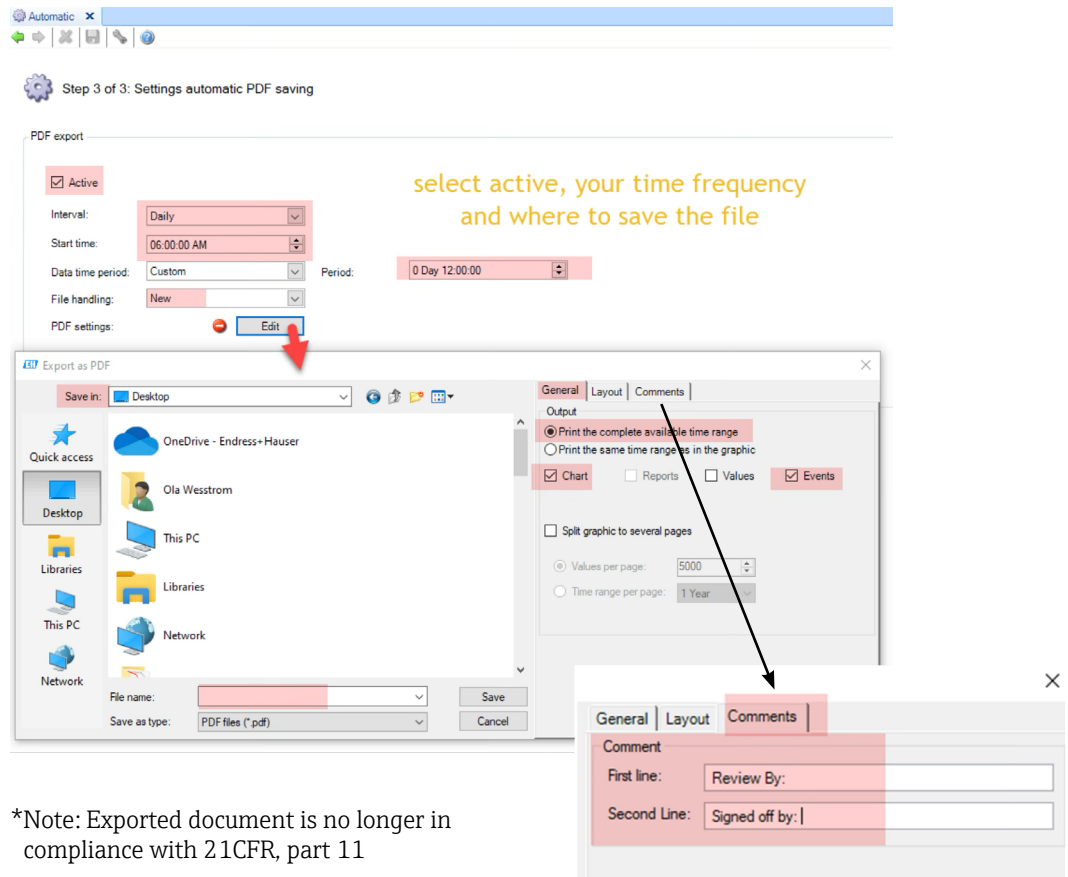
- 1. Go to automatic
- 2. Select new/edit (PDF export)
- 3. Select recorder(template)



*Note: Any exported document is no longer in compliance with 21CFR, part 11

Automatic creation of PDF / other exports* (2)

- Finalize export by selecting time frame and preferences
- Optionally, a comment can be added on the top of page – see example:



*Note: Exported document is no longer in compliance with 21CFR, part 11

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