memmert

AtmoCONTROL

FDA EDITION

IQ DOCUMENTATION
OQ DOCUMENTATION

MADE IN GERMANY.

www.memmert.com

Manufacturer and customer service

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We reserve the right to make changes

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Please follow the instructions below and fill out each gap in order to perform the installation qualification as well as the operational qualification.

Examination object (to be completed by user)

Manufacturer:	MEMMERT GmbH + Co.KG, 91126 Schwabach, Germany
Designation:	Memmert AtmoCONTROL FDA
Version:	
Site:	
Occasion:	

Inspection Personnel (to be completed by user)

	Name	Position	Signature	Date
Performed by:				
Approved by:				

Memmert recommends that the IQ/OQ protocols are performed in total when AtmoCONTROL FDA is initially installed. Installation Qualification should be performed as well when the software is upgraded and when the computer that runs AtmoCONTROL FDA is changed or modified. Operational qualification should also be run on a regular basis to confirm that the system is performing to specification and also when there is any doubt that the instrument is not performing to specifications.

1. Introduction

The task of the FDA is the protection of public health in the US and the approval of pharmaceutical products. The FDA controls the safety and efficacy of medical products for human and veterinary medicine, biological products, medical devices, food and radiation - emitting devices, that arrive in the American market. This applies to products manufactured in the US as well as imported products. FDA plays a significant role in addressing the Nation's counter-terrorism capability and ensuring the security of the food supply.

The Electronic Records and Signatures Rule, known as 21 CFR Part 11, were introduced by the U.S. Food and Drug Administration (FDA) in order to define requirements for the use of electronic documents instead of paper records. The law, published in the Federal Register on March 20, 1997 and in effect since August 20, 1997, specifies the system elements, controls, and procedures that are necessary to make sure the trustworthiness of electronically stored records.

Conformity requires both procedural controls and administrative controls, such as Standard Operating Procedures (SOPs), training and administration to be put in place by the user, in addition to the technical controls and elements that the system can offer. Therefore, no product alone can fully meet the regulatory requirements. However, products with unified functions that support 21 CFR Part 11 requirements can significantly ease the task of achieving and maintaining full conformity with the law.

1.1 Purpose of Qualification

Qualification of instruments or software is a formal process of documenting that an instrument or software is fit for its intended use and that is kept maintained and calibrated.

IQ: The purpose of this qualification is to examine that the product designated as "examination object" is complete and is essentially ready for operation.

It also documents that all important specifications and parameters described by the manufacturer, as well as its safety requirements, are fulfilled.

OQ: The purpose of this qualification is to ensure the function of the product designated as "examination objects" and that it is ready for operation.

The following functions are tested:

- Security functions (according to FDA Titel 21 CFR Part 11)
- Control functions relevant for quality and/or process

2. Installation Qualification

Installation Qualification (IQ) demonstrates that the AtmoCONTROL FDA software is properly installed. Installation Qualification tests should be performed at the following times:

- When the system is installed
- Every time the software is upgraded
- Any time the associated computer is changed or modified
- Prior to running OQ tests

2.1 Packing List Verification

Operating software "AtmoCONTROL FDA Version"on USB stick included?	☐ yes	☐ no
Operating instructions for "AtmoCONTROL FDA Version"on USB stick included ?	☐ yes	☐ no
Is the AtmoCONTROL FDA Version Software USB stick undamaged?	☐ yes	☐ no
No externally visible damage to the USB stick or packaging material?	☐ yes	☐ no
Delivery complete according to order and order confirmation (e.g. Software and Installation Manual)	☐ yes	☐ no

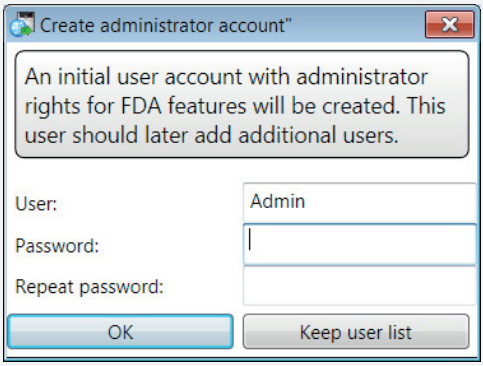
The answer to all questions must be "yes" in order to move on to the next qualification stage, otherwise rectify the fault!

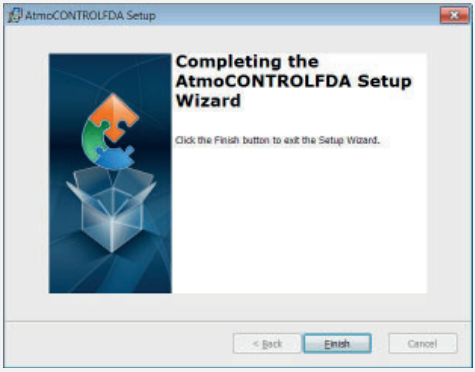
2.2 Software Installation (to be completed by user)

Are the following requirements fulfilled? ▶ Computer is running operating system Windows 7, Windows 8, Windows 10? ▶ Enough internal memory is available for a successful installation (at least 1GB)? ▶ Installer has administrator rights?	☐ yes	☐ no

For the installation process please refer to the AtmoCONTROL User Manual and follow the instructions under Section "Installing AtmoCONTROL." The manual was delivered along with the AtmoCONTROL FDA Version Software USB stick.

Installation

During installation, are you prompted to create an "Admin" account with a password? 	☐ yes	☐ no

Was the software installed successfully? 	☐ yes	☐ no

2.3 Assessment of Installation Qualification

The installation qualification has been passed successfully if all previous questions have been answered with yes. If not, the errors have to be fixed and the installation qualification needs to be repeated.

I hereby confirm that all previous questions have been answered with YES.

Name	Position	Date	Signature

3. Operational Qualification

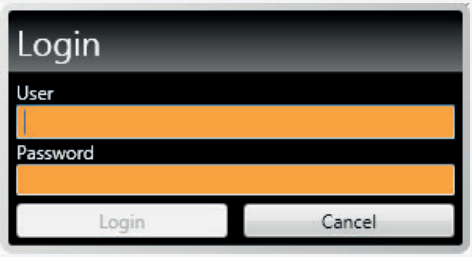
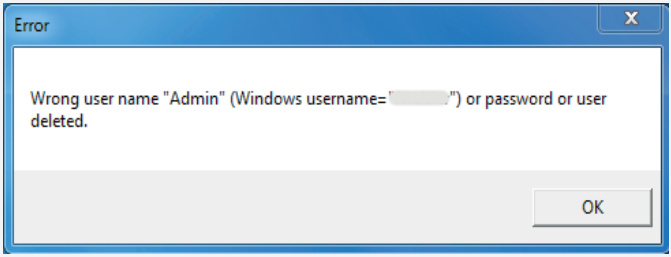
Operational Qualification (OQ) demonstrates that the AtmoCONTROL FDA software is functioning to specification. Operational Qualification tests should be performed:

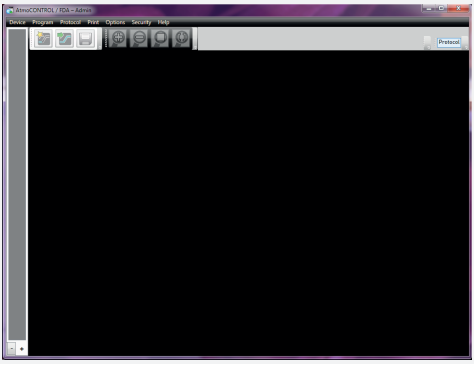
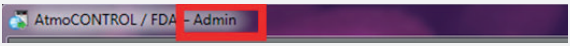
- Once upon receipt of the instrument
- When the computer or software that runs the instrument is changed or modified

Software IQ tests should be performed prior to the OQ tests in order to verify that the software is installed properly.

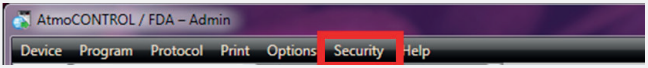
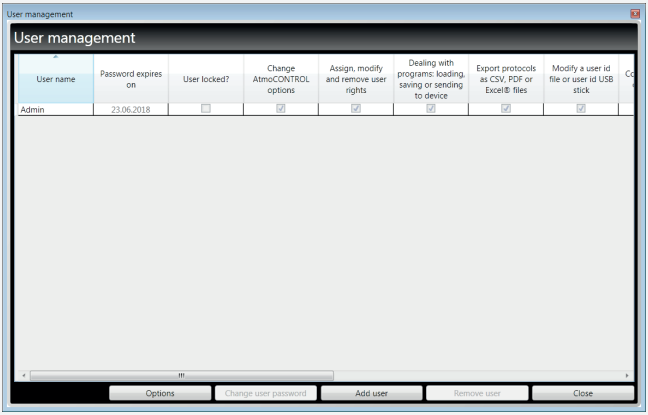
3.1 Login

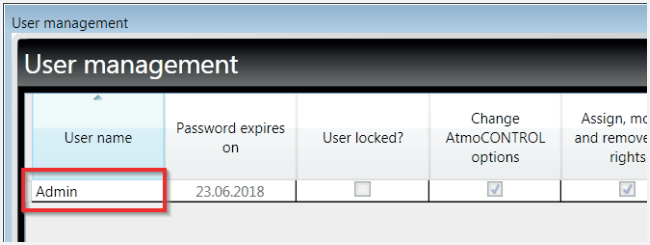
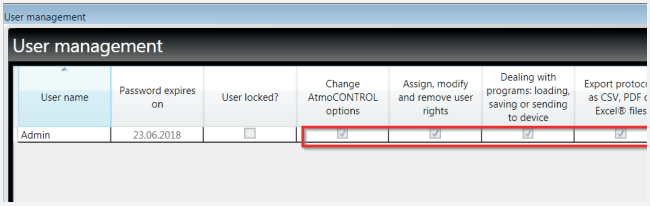
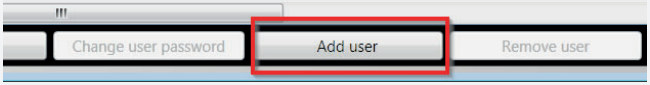
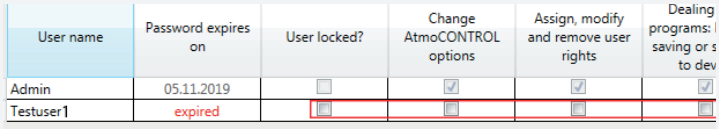
Start the AtmoCONTROL FDA Version by double-clicking the appropriate icon or in the start menu.

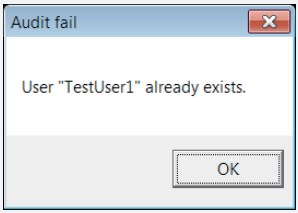
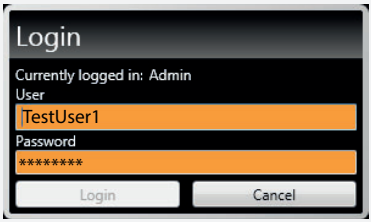
Does the *Login* window appear after starting AtmoCONTROL FDA? 	☐ yes	☐ no
If the username and/or password are incorrect, does the login fail? 	☐ yes	☐ no
Can you login with your user name which was created during Setup?	☐ yes	☐ no

After login, does the program start with the AtmoCONTROL window? 	☐ yes	☐ no
Is *Admin* displayed in the title bar? 	☐ yes	☐ no

3.2 Admin and User Rights

Is the menu item *Security* available? 	☐ yes	☐ no
Does the following window appear after clicking *Edit users* in the *Security* menu? 	☐ yes	☐ no

Does the Admin appear in the list? 	☐ yes	☐ no
Does the Admin have all user rights, is locked and can't be edited? 	☐ yes	☐ no
Does the button *Add user* exist? 	☐ yes	☐ no
Create a new user account by clicking the *Add user* button and name the new user "TestUser1" . 		
Does the new user have no user rights? 	☐ yes	☐ no
Can the user rights be edited?	☐ yes	☐ no

Create a new user account with the same name as before. Does the following message appear? 	☐ yes	☐ no
Can the admin reset the password of "TestUser1" ? 	☐ yes	☐ no
Close the *User Management* window. Click the *Switch user* button in the *Security* menu. Can you login as "TestUser1"? 	☐ yes	☐ no
Is "TestUser1" displayed in the title bar? 	☐ yes	☐ no

User Rights

Login as "TestUser1". Check if it is not possible to change the system settings (*Options* → *Email options* or *Edit backup folder*) Is it impossible?	☐ yes	☐ no
Check if it is not possible to open the *User management* (*Security* → *Edit user*) Is it impossible?	☐ yes	☐ no

Audit Trail

Login as Admin. To confirm the functionality of the *Audit Trail* function, select the *Security* tab on top of the tool bar and click on *Audit Trail*. Is the *Audit Trail* window below displayed? 	☐ yes	☐ no
Does the *Audit Trail* window appear without any error messages?	☐ yes	☐ no
Activate *Select time span*. Is it possible to select the current day as time span? 	☐ yes	☐ no

Click the *Show audit trail* button. Does it open up the following browser window?

Audit Trail AtmoCONTROL / FDA

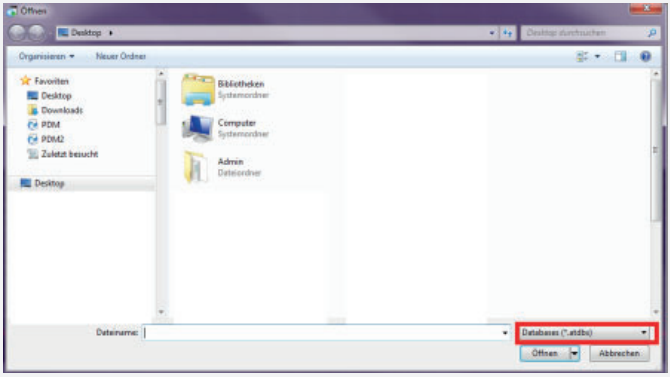
Created by: Admin (Karl)
Created on: 02.05.2018 11:06
Time range: 31.01.2018 00:00:00 - 02.05.2018 23:59:59
Computer: HP
Version: 2.6.0.0 16.03.2018 14:00

Type	Date/Time	User	Description
Audit OK	31.01.2018 16:53:11	(Karl)	User "Admin" logged onto AtmoCONTROL
Audit OK	31.01.2018 16:53:20	Admin	Checked access rights "Connecting to an offline device".
Audit OK	31.01.2018 16:53:31	Admin	Checked access rights "Connecting to an online device".
Audit OK	31.01.2018 16:54:42	Admin	Checked access rights "Dealing with programs: loading, savi
Info	31.01.2018 16:54:54	Admin	Program saved to file "C:\Users\Karl\AppData\Local\Memme
Audit OK	31.01.2018 16:55:15	Admin	Checked access rights "Signing 'created'".
Info	31.01.2018 16:55:15	Admin	Document "C:\Users\Karl\AppData\Local\Memmert\AtmoCor
Info	31.01.2018 16:55:15	Admin	Program saved to file "C:\Users\Karl\AppData\Local\Memme
Audit OK	31.01.2018 16:56:23	Admin	Checked access rights "Dealing with programs: loading, savi
Info	31.01.2018 16:57:20	Admin	Program saved to file "C:\Users\Karl\AppData\Local\Memme

☐ yes ☐ no

3.3 Connect database

To confirm the functionality of the *Connect database* function, click *Device → Connect offline from Database*. Does the following window appear?

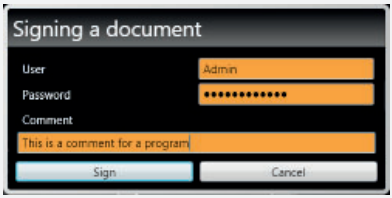
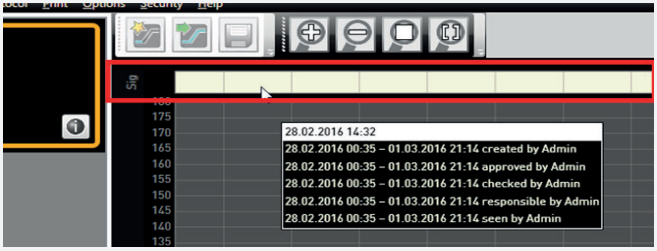
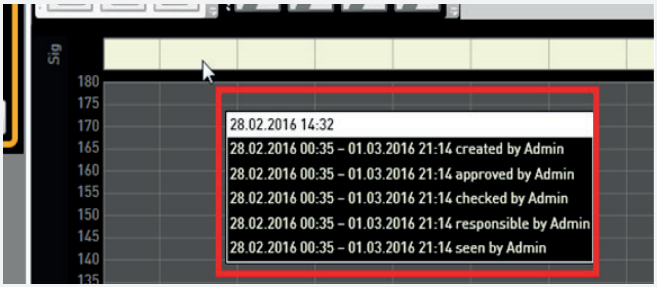


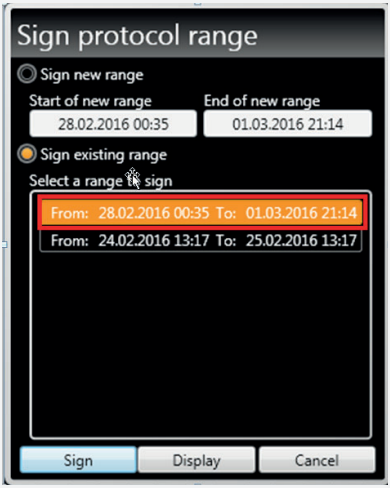
Connect demo device Y6160011.atdbx .

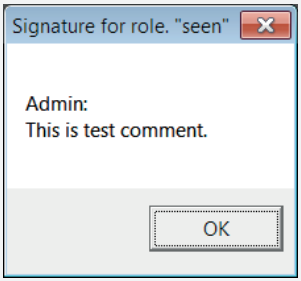
☐ yes ☐ no

3.4 Signatures

Click the *Security* button. Can the *Sign document* button be selected?	☐ yes	☐ no
Does the following window appear? 	☐ yes	☐ no
Can the starting and ending point for signatures be selected? 	☐ yes	☐ no
Does the following window appear after clicking the *Sign* button? 	☐ yes	☐ no
Can all five roles be selected? 	☐ yes	☐ no

Does the following window appear after clicking the *Sign* button? 	☐ yes	☐ no
Enter the admin data. Does the *Signature* window close without any errors after clicking the *Sign* button?	☐ yes	☐ no
Does the new signature appear in the signature bar? 	☐ yes	☐ no
Do all informations appear in the signature bar after moving the cursor over the bar? 	☐ yes	☐ no

Select the *Security* tab from the top tool bar and click *Sign document*. Does the window *Sign protocol range* show the newly created signature? 	☐ yes	☐ no
Can the newly created signature be selected? 	☐ yes	☐ no

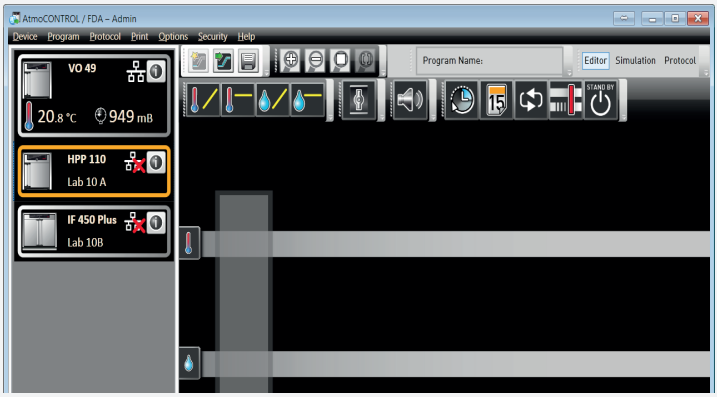
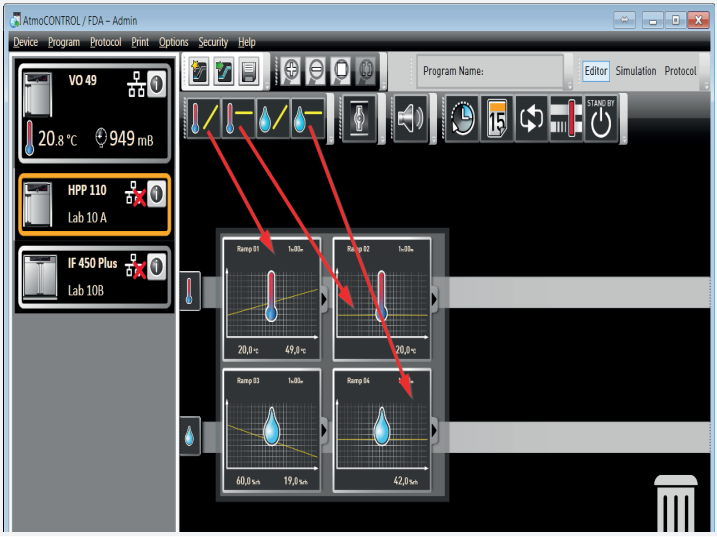
Does the *Select roles to sign* window appear after clicking the *Sign* button and is the admin shown in every role? 	☐ yes	☐ no
After clicking on an info symbol , is the comment redisplayed?  Close the dialog by clicking the *Cancel* button.	☐ yes	☐ no

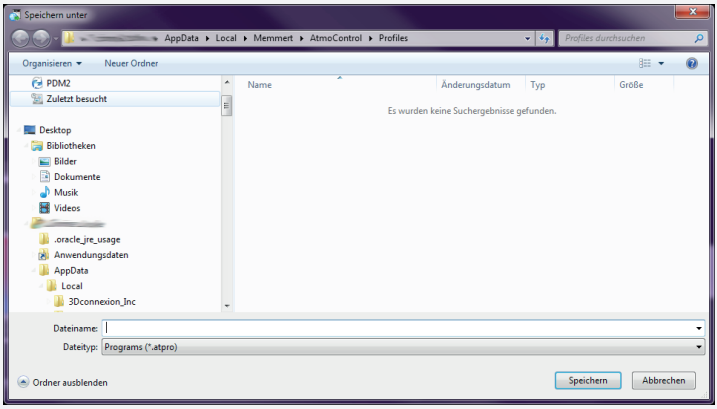
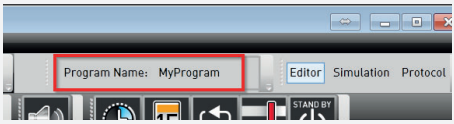
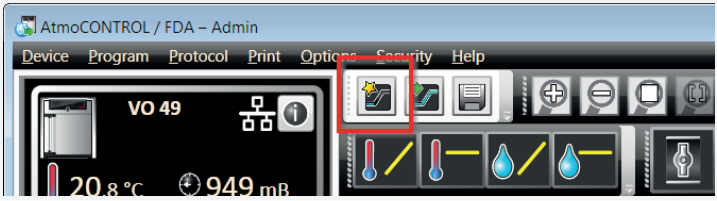
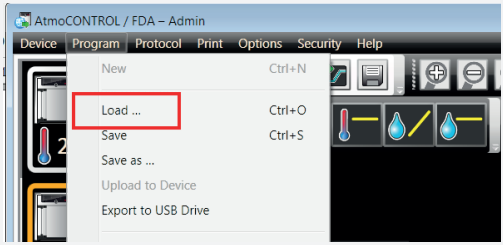
Security

Login with the newly created user account, without user rights. Is it possible?	☐ yes	☐ no
Check if it is possible to sign the protocol as "TestUser1". Is it impossible?	☐ yes	☐ no

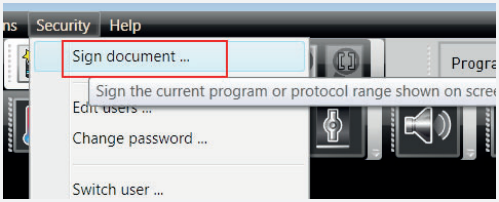
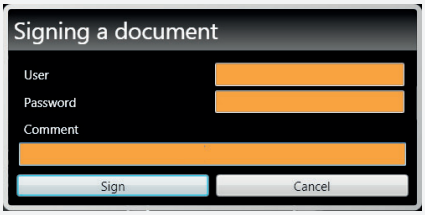
Close the dialog by clicking the *Cancel* button.

3.5 Editor

Login as Admin. Switch to the *Editor* view. Does AtmoCONTROL FDA show the following window? 	☐ yes	☐ no
Can you create a new profile by dragging and dropping the program symbols? 	☐ yes	☐ no

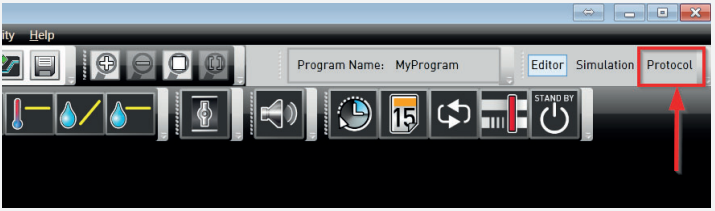
Save the new profile. Can it be saved? 	☐ yes	☐ no
Does the selected filename appear in the program view? 	☐ yes	☐ no
Click *New program*. Are all program elements removed? 	☐ yes	☐ no
Click *Program*. Open the previously saved program. Is it possible? 	☐ yes	☐ no

Signatures

Can you select the menu item *Sign document*? 	☐ yes	☐ no
Does the window *Select roles to sign* appear after clicking the *Sign* button? 	☐ yes	☐ no
Can all five roles be selected? 	☐ yes	☐ no
Does the following window appear after clicking the *Sign* button? 	☐ yes	☐ no
Enter the admin data. Does the *Signature* window close without any errors after clicking the *Sign* button?	☐ yes	☐ no

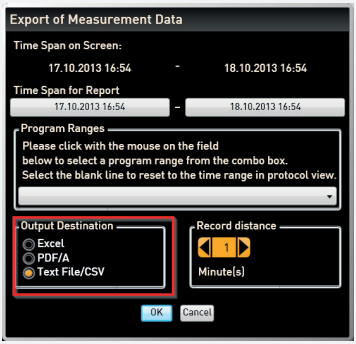
Does the *Select roles to sign* window appear after clicking the *Sign* button and show the admin in every role? 	☐ yes	☐ no
Close the dialog by clicking the *Cancel* button. Does the editor show a lock symbol in the top left corner? 	☐ yes	☐ no
Try to move the editor symbols around. Are they blocked resp. is the program write-protected?	☐ yes	☐ no

3.6 Export

Switch to *Protocol* view. 		

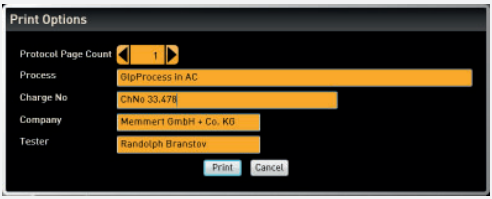
Does the *Export of Measurements Data* window appear after clicking *Protocol → Export*? 	☐ yes	☐ no
Can the desired time span be selected? 	☐ yes	☐ no

Can you select the following items:		
▶ Excel	☐ yes	☐ no
▶ PDF	☐ yes	☐ no
▶ Text File/CSV	☐ yes	☐ no

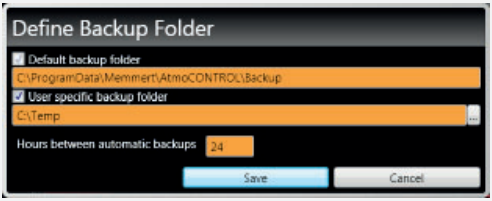
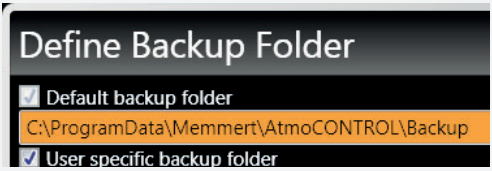


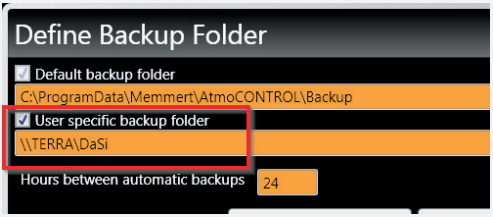
Does the window show an input mask for the GLP data when selecting Excel or PDF?	☐ yes	☐ no

Can the protocol be exported to all three files types?		
▶ Excel	☐ yes	☐ no
▶ PDF	☐ yes	☐ no
▶ Text File/CSV	☐ yes	☐ no

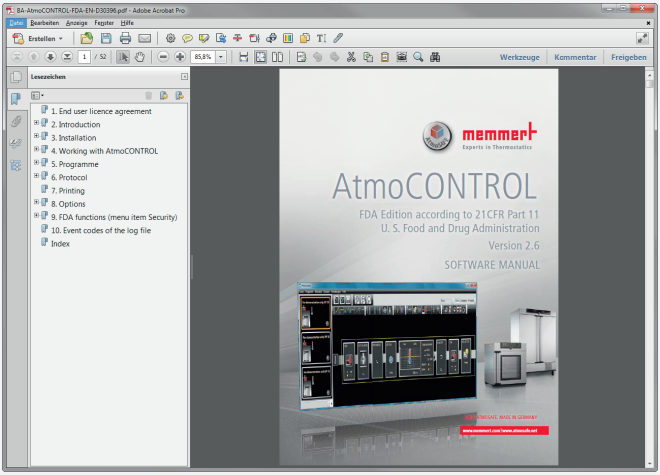
Does the following window appear after clicking the *Print document* button? 	☐ yes	☐ no
Please fill the gaps and print the protocol. Does the printout contain the signatures? 	☐ yes	☐ no
Does AtmoCONTROL print the document without any errors?	☐ yes	☐ no

3.7 Backup

Does the following window appear after clicking *Edit backup folder* in the *Options* menu? 	☐ yes	☐ no
If *Default backup folder* is activated, is it impossible to deactivate it? 	☐ yes	☐ no
Is the path write-protected?	☐ yes	☐ no
Activate *User specific backup folder*. Is it possible to edit the folder?	☐ yes	☐ no

Activate *User specific backup folder* and click *Save*. Close the dialog by clicking the *Cancel* button. Reopen the dialog and be sure that the changes are present. 		
Deactivate *User specific backup folder* and click *Save*. Does the window close without any errors?	☐ yes	☐ no

3.8 Help

Does the following window appear after clicking the *About* button in the *Help* menu and show the activated version? 	☐ yes	☐ no
Does the following PDF document appear after clicking *User manual* in the *Help* menu? 	☐ yes	☐ no

3.9 Assessment of Operational Qualification

The operational qualification has been passed successfully if all previous questions have been answered with Yes. If not, the errors have to be fixed and the operational qualification needs to be repeated.

I hereby confirm that all previous questions have been answered with YES.

Name	Position	Date	Signature

memmert

AtmoCONTROL FDA Edition

IQ Documentation
OQ Documentation

D39051 | Date 12/2019 | v2.9

englisch

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