

AtmoCONTROL EDA EDITION

IQ DOCUMENTATION OQ DOCUMENTATION



Manufacturer and customer service

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AtmoCONTROL FDA Edition – IQ-OQ-Documentation

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.

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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 counterterrorism 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.

<u>IQ</u>: 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.

<u>OQ</u>: 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 in- cluded? | □ 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?

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, with a password? | are you prompted to creat | e an "Admin" account | | |
|---|---|----------------------|-------|------|
| 🐼 Create administrato | r account" | l l | | |
| An initial user accorrights for FDA feat user should later a | ount with administrator ures will be created. This dd additional users. | | □ yes | 🗆 no |
| User: | Admin | | | |
| Password: | l, | | | |
| Repeat password: | | | | |
| ОК | Keep user list | | | |

Was the software installed successfully?



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 |
|------|----------|------|-----------|
| | | | |
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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.



| 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? | | |
|--|-------|------|
| 💑 AtmoCONTROL / FDA – Admin | 🗆 yes | □ no |
| Device Program Protocol Print Options Security Help | | |
| Does the following window appear after clicking <i>Edit users</i> in the Security menu? | □ yes | □ no |

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| Does the Admin appear in the list? | | |
|---|-------|------|
| User management User management User name Password expires on User locked? AtmocONTROL options and remove rights Admin 23.06.2018 | □ yes | □ no |
| Does the Admin have all user rights, is locked and can't be edited? | □ yes | □ no |
| Does the button Add user exist? Change user password Add user Remove user | □ yes | 🗆 no |
| Create a new user account by clicking the Add user button and name the new user "TestUser1" . Add user Username TestUser1 Password Cancel Add user | | |
| Does the new user have no user rights? User name Password expires on User locked? Change AtmoCONTROL options Assign, modify and remove user rights Dealing programs: I saving or s to dev Admin 05.11.2019 Image: Change Atmocontraction of the saving | □ 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" ? Change password Change password Change password Change password Cancel Change password Cancel Change password | □ yes | □ no |
| Close the User Management window. Click the Switch user button in the Security menu. Can you login as "TestUser1"? Login Currently logged in: Admin User TestUser1 Password ******** Login Cancel | □ yes | □ no |
| Is "TestUser1" displayed in the title bar? AtmoCONTROL / FDA - TestUser1 Device Program Protocol Print Options Security Help Device Program Protocol Print Options Security Help | □ yes | □ no |



User Rights

| Login as "TestUser1". | | |
|--|-------|------|
| Check if it is <u>not</u> possible to change the system settings (Options \rightarrow Email options or Edit backup folder) | | |
| Is it impossible? | 🗆 yes | 🗆 no |
| Check if it is <u>not</u> possible to open the User management (Security \rightarrow 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?

| Audit Trail Select all Select time span From To Januar 2018 Mail 2018 Mo Di Mi Do Fr Sa So 22 22 22 27 27 28 20 21 1 2 2 23 4 5 6 7 1 5 9 10 11 12 11 14 1 5 9 10 11 12 11 14 15 12 11 14 1 2 2 23 4 25 20 27 28 29 20 11 1 1 2 11 14 Show Audit Trail Export Audit Trail Cancel | □ 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 I | by: Admin (Karl) | | | | |
|-----------|---------------------|-------------|--|-------|---|
| Created | on: 02.05.2018 1 | 1:06 | | | |
| Time ran | ge: 31.01.2018 (| 0:00:00 - (| 02.05.2018 23:59:59 | | |
| Compute | er: HP | | | | |
| Version: | 2.6.0.0 16.03 | 3.2018 14:0 | 10 | _ | |
| Туре | Date/Time | User | Description | ∐ yes | L |
| 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 | | |
| | | | and the second and the second se | | |

3.3 Connect database

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



Connect demo device Y6160011.atdbx .



3.4 Signatures

| Click the <i>Security</i> button. Can the <i>Sign document</i> button be selected? | 🗆 yes | 🗆 no |
|---|-------|------|
| Does the following window appear? | | |
| Sign protocol range Sign new range Start of new range 17:10:2013:16:54 Sign existing range Select a range to sign Sign Display Cancel | □ yes | □ no |
| Can the starting and ending point for signatures be selected? | | |
| Sign protocol range Sign new range Information new range Information new range Select a range to sign Select a range to sign Circum Directory | □ yes | □ no |
| Does the following window appear after clicking the Sign button? | | |
| Select roles to sign created seen checked seproved Sign Cancel | □ yes | □ no |
| Can all five roles be selected? | | |
| Select roles to sign created seen checked approved responsible Sign Cancel | □ yes | □ no |



| Does the following window appear after clicking the Sign button? | | |
|--|-------|------|
| Signing a document User Admin Password | □ yes | □ no |
| Enter the admin data. | | |
| Does the <i>Signature</i> window close without any errors after clicking the <i>Sign</i> 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 |

| Se | lect the Se | <i>curity</i> tab fr | om the top t | tool bar and click Sign document. | | |
|----------|---|--|------------------------------------|-----------------------------------|-------|------|
| Do tu | pes the win re? | idow Sign p | rotocol rang | e show the newly created signa- | | |
| S | ign proto Sign new rang Start of new rang | pcol range e ge <u>End of n</u> | ew range | | | |
| | 28.02.2016 () Sign existing ra Select a range to From: 28.02. | 00:35 01.0 ange 5 sign 2016 00:35 To: 01 | 03.2016 21:14 1.03.2016 21:14 | | □ yes | 🗆 no |
| | From: 24.02. | 2016 13:17 To: 2 | 600col | | | |
| | sign | Display | Cancel | elected? | | |
| | Sign prote | ocol range | new range | | | |
| | Sign existing r Select a range t From: 28.02 From: 24.02 | ange * sign .2016 00:35 To: 0 .2016 13:17 To: 2 | 1.03.2016 21:14 5.02.2016 13:17 | | □ yes | □ no |
| | | | | | | |
| | Sign | Display | Cancel | | | |

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| Does the Sele button and is | ect roles to sign window appear after clicking the Sign the admin shown in every role? | | |
|--------------------------------|--|-------|------|
| Select role | es to sign | | |
| created | Admin | | |
| seen | Admin 🗆 💽 | 🗆 yes | 🗆 no |
| checked | Admin 🗆 💽 | | |
| approved | Admin | | |
| responsible | Admin | | |
| Sign | Cancel | | |
| After clicking | on an info symbol 🖳 is the comment redisplayed? | | |
| Signature for r | ole. "seen" | | |
| | | | |
| Admin: | | | |
| This is test co | mment. | □ yes | □ no |
| | | | |
| | ОК | | |
| | | | |
| Close the dial | og by clicking the Cancel button. | | |

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?



Can you create a new profile by dragging and dropping the program symbols?











□ yes

□ yes

□ yes

🗆 no

🗆 no

□ no

Signatures

Can you select the menu item Sign document?

| Security Help | | | |
|-----------------------|--|-------|--|
| Sign document | Progra | | |
| Sign the current prog | ram or protocol range shown on scree | 🗆 yes | |
| Change password | | | |
| Switch user | | | |
| and the window Color | t voloo to sign annoav after didling the Cig | | |

Does the window *Select roles to sign* appear after clicking the *Sign* button?

| Select role | es to sign |
|-------------|------------|
| created | |
| seen | |
| checked | |
| approved | |
| responsible | |
| Sign | Cancel |

Can all five roles be selected?

| Select roles to sign | | | | |
|----------------------|--|------|---|--|
| created | | | × | |
| seen | | | × | |
| checked | | | × | |
| approved | | | × | |
| responsible | | | × | |
| Sign Cancel | | icel | | |

Does the following window appear after clicking the Sign button?

| Signing a document | | |
|---|--------|--|
| User | | |
| Password | | |
| Comment | | |
| 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 | | |
| Sign | Cancel | |

Enter the admin data.

Does the Signature window close without any errors after clicking the \Box yes \Box no Sign button?

| 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. | | | |
|--|--|--|--|
| | | | |
| ity <u>H</u> elp | | | |
| Program Name: MyProgram Editor Simulation Protocol | | | |
| | | | |
| | | | |
| | | | |

| Does the Export of Measurements Data window appear after clicking Protocol → Export? Export of Measurement Data Time Span on Screen: 17.10.2013 16:54 - 18.10.2013 16:54 Trane Span for Report 17.10.2013 16:54 - 18.10.2013 16:54 Please click with the mouse on the field below to select a program range from the combo box. Select the blank line to reset to the time range in protocol view. Output Destination Company BipProcess in AC Company Charge No Charge No Cancel | □ yes | 🗆 no |
|---|-------|------|
| Can the desired time span be selected? | □ yes | 🗆 no |

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| Can you select the following items: | | |
|--|-------------------------|----------------------|
| ► Excel | □ yes | □ no — |
| PDF | ∐ yes | ∐ no |
| Export of Measurement Data Time Span on Screen: 17.10.2013 16:54 - 18.10.2013 16:54 Time Span for Report 17.10.2013 16:54 - 18.10.2013 16:54 Program Ranges Please cick with the mouse on the field below to select a program range from the combo box. Setect the blank line to reset to the time range in protocol view. Setect the blank line to reset to the time range in protocol view. Setect the blank line to reset to the time range in protocol view. Setect the blank line to reset to the time range in protocol view. Setect the blank line to reset to the time range in protocol view. Minute(s) Minute(s) | L yes | |
| Does the window show an input mask for the GLP data when selecting | | |
| Export of Measurement Data Time Span on Screen: 17.10.2013 16:54 - 18.10.2013 16:54 Time Span for Report 17.10.2013 16:54 - 18.10.2013 16:54 Program Ranges Please (Lick with the mouse on the field below to select a program range from the combo box. Select the blank line to reset to the time range in protocol view. Select the blank line to reset to the time range in protocol view. Cutput Destination Excel PDF/A For Etip/CSV Cancel | □ yes | □ no |
| Can the protocol be exported to all three files types? Excel PDF Text File/CSV | □ yes □ yes □ yes | □ no □ no □ no |

| Does the following window button? | w appear after clicking the Print | document | |
|---|---|------------|------|
| Print Options | | | |
| Protocol Page Count 🖌 1 🕨 | | | |
| Process GinProcess in AC | | 🗆 ves | 🗆 no |
| Charge No ChNo 33.478 | | , | |
| Company Memmert 6mbH + Co. KB | | | |
| Tester Randolob Brancton | | | |
| International Protocol | | | |
| Print Can | AL . | | |
| · | | | |
| Please fill the gaps and prin | nt the protocol. | | |
| Doos the printout contain | the signatures? | | |
| Does the philtout contain | the signatures? | | |
| | | | |
| Process: OQ-Test | Page: 2/2 | | |
| Charge No: 0000 C | ompany: [Company] Tester: [Tester | ri 🗆 🗆 ves | 🗆 no |
| Time Pancer 28.02 2016 00:35 - 01.03 2016 21:14 | enal Number: D4130050 Signature: | | |
| Time Range: 200212010 0000 - 01002010 2111 | | | |
| Signatures | | | |
| From To Signed I | y Signed On Role | | |
| 28.02.2016 00:35 01.03.2016 21:14 Admin | 11.04.2016 0934 approved 11.04.2016 0934 checked | | |
| | | | |
| Does AtmoCONTROL print | the document without any error | rs? □ ves | 🗆 no |

3.7 Backup

| Does the following window appear after clicking <i>Edit backup folder</i> in the <i>Options</i> menu? | □ yes | □ no |
|---|--------|------|
| If Default backup folder is activated, is it impossible to deactivate it? | | |
| Define Backup Folder | | Про |
| Default backup folder C\ProgramData\Memmert\AtmoCONTROL\Backup | Ll yes | |
| ✓ User specific backup folder | | |
| Is the path write-protected? | 🗆 yes | 🗆 no |
| Activate User specific backup folder. Is it possible to edit the folder? | □ yes | □ no |

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| 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. | | |
|--|-------|------|
| Define Backup Folder | | |
| C Default backup folder C \ProgramData\Memmert\AtmoCONTROL\Backup C User specific backup folder (\TERRA\DaSi Hours between automatic backups 24 | | |
| 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?



in the Help menu?





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 |
|------|----------|------|-----------|
| | | | |
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AtmoCONTROL FDA Edition

IQ Documentation OQ Documentation

D39051 | Date 12/2019 | v2.9 englisch

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