DatPass v4.0 User Guide

FDA 21 CFR Part 11 Compliant

Supporting DataSuite, DataNet and MicroLab Software

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Contents

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To download updated versions of the DatPass User Guide and software visit:
www.fourtec.com

Chapter 1.
Introduction

DatPass is administration software compatible with FDA 21 CFR Part 11 and supporting the assignment of passwords and operating privileges for fourtec industry application software.

DatPass works with the following fourtec software:
- DataSuite – supporting DataNet, DaqLink, MicroLogPRO II, MicroLite and PicoLite data loggers
- DataNet – supporting DataNet data loggers
- MicroLab – supporting MicroLog and MicroLogPRO data loggers

DatPass defines the users that can log onto DatPass, their passwords, digital signatures and the action they are permitted to take.
DatPass also maintains an audit trail that keeps track of all users' activities.
Together with DataSuite, DataNet and MicroLab, DatPass forms a dual program software package that complies with FDA Title 21 CFR Part 11.

Associated Documentation

- DataSuite User Guide
- DataNet for CFR User Guide
- MicroLab for CFR User Guide
- DatPass and DataSuite CFR Validation Manuals
- DatPass and DataNet CFR Validation Manuals
- DatPass and MicroLab CFR Validation Manuals

Chapter 2.
Installing DatPass

System Requirements

To work with DatPass, and support fourtec software, your system should be equipped with the following:

Software
- Windows XP, Vista or Windows 7
- Microsoft .NET Framework 3.5

Hardware
- Pentium 300 MHz or higher
- 32 MB RAM (64 MB recommended)
- 5 MB available disk space

Installing the Software

> **Note:** Existing users of DatPass v2.0 are able to upgrade to DatPass v4.0 and continue to use their existing audit trail database. Refer to the section on *Existing DatPass Users* below.

First-time DatPass Users

1. Insert the DatPass CD into your CD drive.
2. Enter the DatPass folder on the CD and click the setup.exe file.
3. The DatPass software installation process will begin. Follow the on-screen instructions to complete the DatPass installation.
4. The Wizard first downloads and installs Microsoft .NET Framework 3.5, if not already detected on the computer. The DatPass software requires this platform in order to run. Follow the installation instructions to install the .NET Framework on your PC. This step can take up to two minutes to complete. Click **Finish** once installation is complete.
   > **Note:** If .NET Framework is already installed on your computer this step is skipped.
5. The main DatPass Installation Wizard now resumes. Once complete, launch the

   software via the DatPass desktop shortcut .
6. The DatPass software will now prompt the user to activate the software or commence the 30-day free trial period. Until either of these steps are performed, DatPass cannot be accessed.
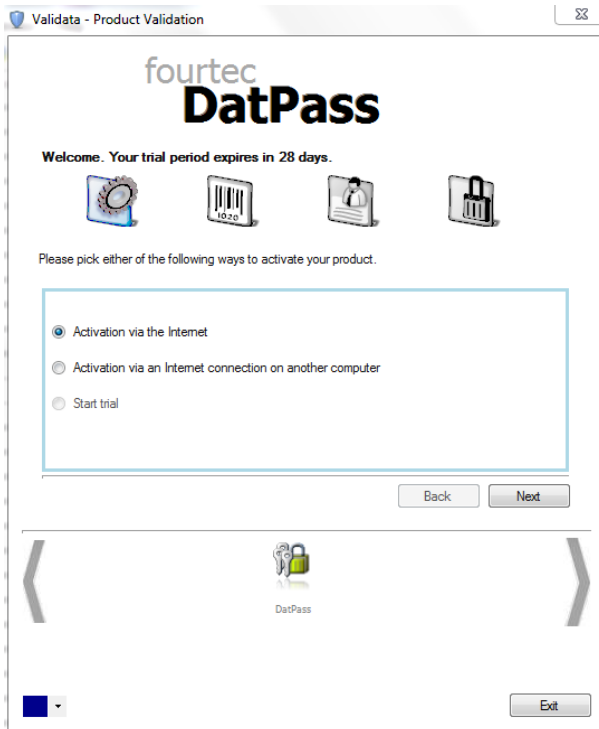
7. Select **Start trial** to commence the free 30-day trial and click **Next,** or select the relevant activation options. A unique Serial Number is required, and it is included in your product packaging. Refer to Chapter 3 regarding DatPass activation.

8. DatPass will launch following completion of the activation process. The user will then be prompted for login details in order to access the software.
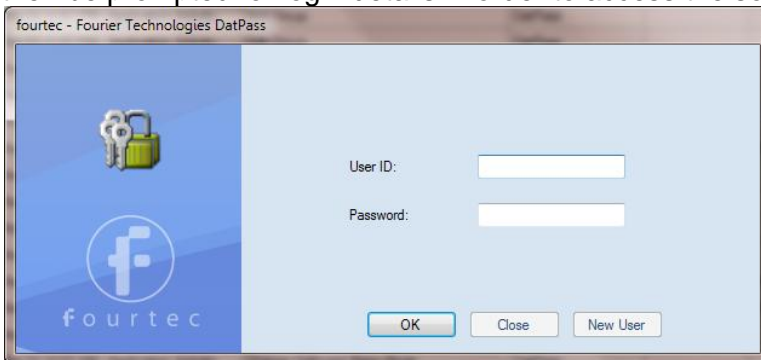
Refer to Chapter 4 for more details on first-time use.

9. After installing DatPass on your computer for the first time, the DatPass database (file name: Current.mdb) will be created in the following default path: *\Users\Public\fourtec\DatPass.*
Users with DatPass Admin privileges can choose to move the database to another location via the DatPass Move Database feature. Refer to Chapter 9 for more details.

Existing DatPass Users

Using the current database

Existing DatPass v2.0 users are able to upgrade to DatPass v4.0 and continue to use their existing audit trail database.

During installation of DatPass v4.0, the software will detect a previous DatPass installation on the computer. A new database will therefore not be created. However, DatPass v4.0, when first launched, will attempt to open the existing database from the default path of *\Users\Public\fourtec\DatPass.*

As the existing database is not located here, the user will then be prompted to locate the missing database. The user simply needs to browse to the path of the existing database using the password *fourteccfr*, and DatPass v4.0 will then launch with the existing database and audit trail intact, with the pre-existing login details.

Uninstalling Existing DatPass v2.0

It is not recommended to maintain more than one installation of DatPass on the computer. Therefore, previous versions should be uninstalled only after DatPass v4.0 is successfully installed.

Note that uninstalling DatPass v2.0 will also delete the Current.mdb file from the v2.0 default database path of My Documents/Fourier Systems/DatPass.

For any installation where the database is located in this default path, it is critical that prior to commencing the uninstall process, the user backs up the Current.mdb or simply moves the database to another location, to avoid having it deleted following uninstall.

Installing DataSuite, DataNet or MicroLab Software

DatPass Admin software records the actions of users working in DataSuite, DataNet and MicroLab CFR software. Therefore, each of these applications must also be installed, on the same PC or network as the DatPass installation.

You will find the DataSuite, DataNet or MicroLab CFR software available for installation on your DatPass software CD. Please refer to the user guides of the above-mentioned software for installation instructions.

Once DatPass is installed, and user IDs are created, users of DataSuite, DataNet and MicroLab CFR software will be available to login to the software and operate the loggers.

Installation Troubleshooting

Windows Vista Users

When launching DatPass for the first time, if the Current.mdb database is not found by the software it is because it has not been created in the default path during DatPass installation. The user will then be prompted to locate the missing database, where a copy can always be found in the DatPass directory on \Program Files\fourtec\DatPass. It is recommended to move the database to either the default path of *\Users\Public\fourtec\DatPass* or to another location of your choice.

Chapter 3.
Activating the DatPass Software

> **Note:** The software activation forms are all case sensitive. Incorrect entry will result in invalid registration.

To register the DatPass software follow the instructions below:

1. Locate the DatPass module serial number (SN). The SN label is found on the DatPass software CD case.

> **Note:** If you cannot locate your DatPass serial number, or you are an existing DatPass user upgrading to DatPass v4.0, contact your fourtec distributor or fourtec Customer Support directly in order to receive the serial number.

2. Launch DatPass. The registration wizard will open.

3. To open the registration wizard from within DatPass go to **Help > Register**.

4. From the bottom of the wizard Home screen, select the DatPass icon.

5. Three choices are presented. Select the relevant option and click **Next** to proceed:

   - **Activation via the Internet**

     Select to proceed with registration on the same computer on which DatPass is running, ensuring it has a live Internet connection.

   - **Activation via an Internet connection on another computer**

     Select if the computer on which DatPass is running does not currently have Internet connectivity.

   - **Start trial**

     Select to commence the 30 day free trial period and continue working in DatPass.

6. After selecting one of the two available options for continuing with the registration process, and after clicking **Next** in step 4 above, you will be prompted to enter the software SN. Enter the SN and click **Next**.

> **Note:** Each serial number provides a single user license. You cannot use a serial number already registered on another computer.

7. The registration process now differs, depending on which option was selected in step 5 above. Read the relevant section below for further registration instructions.

Activation via the Internet

1. After entering the software serial number, a window requesting basic personal information will open. Enter the mandatory fields and click **Next**.

2. DatPass will now establish communication with the fourtec server to complete the registration process. If successful, a confirmation message will appear. In the event of any problem in the registration process, please contact your fourtec distributor or fourtec Customer Support.

3. Click **Close** to return to the DatPass software.

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Activation via Internet Connection on another Computer

1. After entering the software serial number, a window providing additional registration instructions will open.

2. Follow the steps as outlined in the window.

> **Note:** It is recommended to generate a text file containing both the Application Key and the Web registration form URL. Press the icon. Transfer this file to the computer with Internet connection, as the registration process must be continued from there.

3. Record the License Key obtained from the Web registration form. Enter it into the License Key field in Step 1 and click **Unlock**.

4. DatPass will now establish communication with the fourtec server to complete the registration process. If successful, a confirmation message will appear. In the event of any problem in the registration process, please contact your fourtec distributor or fourtec Customer Support.

5. Click **Close** to return to the DatPass software.
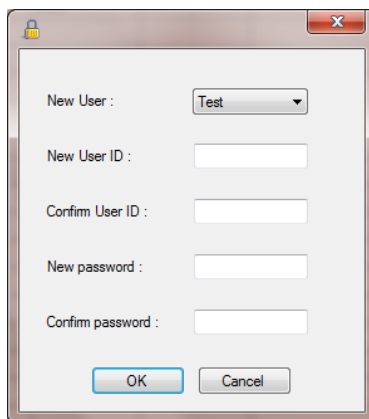
Chapter 4.
First Time Running DatPass

The first user that opens DatPass is automatically assigned as an Administrator and is given the user name Admin. To start working with DatPass the administrator needs to define his own user ID and password:

1. Double click the **DatPass** icon on your desktop to display the **User Login** dialog box:
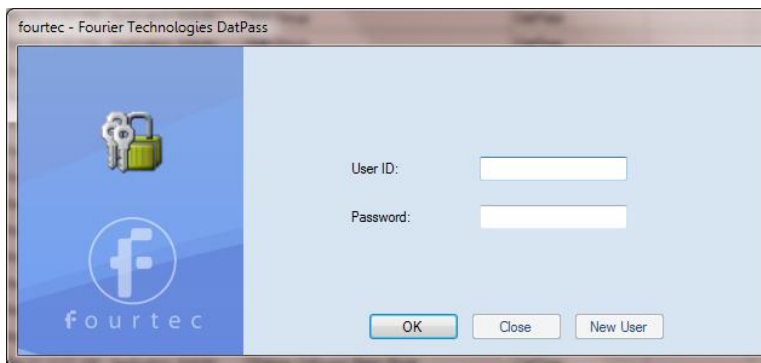
2. Click **New User.**

3. Enter a user ID in the **New User ID** text box.
4. Confirm the user ID in the **Confirm User ID** text box.
5. Enter a password in the **New Password** text box.

Note: The password is case sensitive

6. Confirm the password in the **Confirm Password** text box.
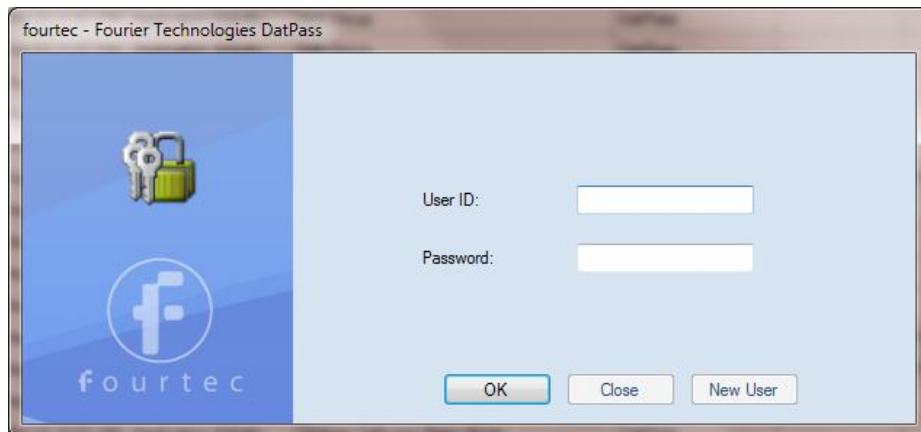7. Click **OK**.

The User ID and Password created here can also be used to access the supported fourtec software.

Chapter 5.
DatPass Login

Existing Users

1. Double click the **DatPass** icon on your desktop to display the **User Login** dialog box:
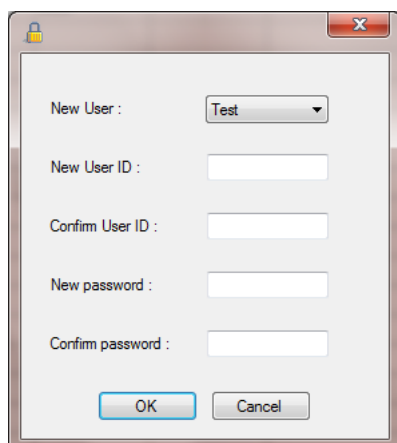

2. Enter your user ID and password, and then click OK.

New Users

You can only login as a new user to DatPass and supported fourtec software if the Admin has created a new user in DatPass.

1. Double click the **DatPass** icon on your desktop to display the **User Login** dialog box.
2. Click **New User**.

3. Select your user name in the **New User** text box.
4. Enter a user ID in the **New User ID** text box.
5. Confirm the user ID in the **Confirm User ID** text box.
6. Enter a password in the **New Password** text box.

> **Note:** The password is case sensitive

7. Confirm the password in the **Confirm Password** text box.
8. Click **OK**.

Chapter 6.
User Administration

> **Note:** If are working in an archived audit trail (refer to Chapter 8 on page 21), then to access **User Administration** you must first exit DatPass and login again to load the Current database.
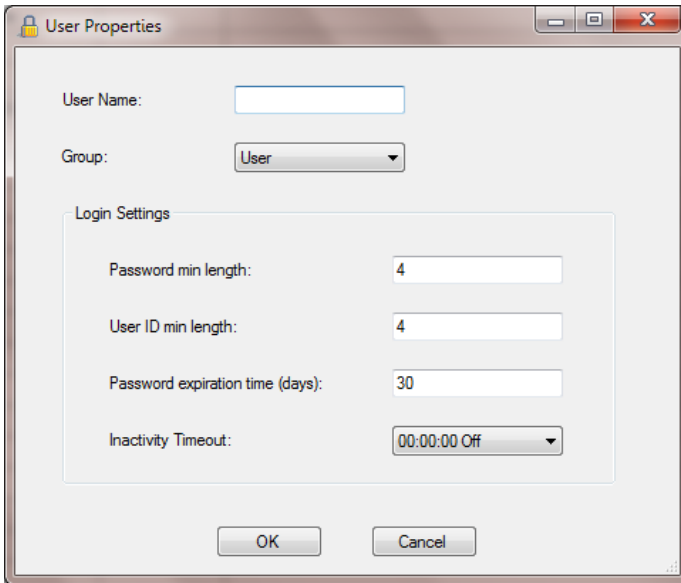
Adding a User

An administrator can add new users, assign privileges to the user and set the login preferences.

To add a new user:

1. Click **User Administration** on the main toolbar.
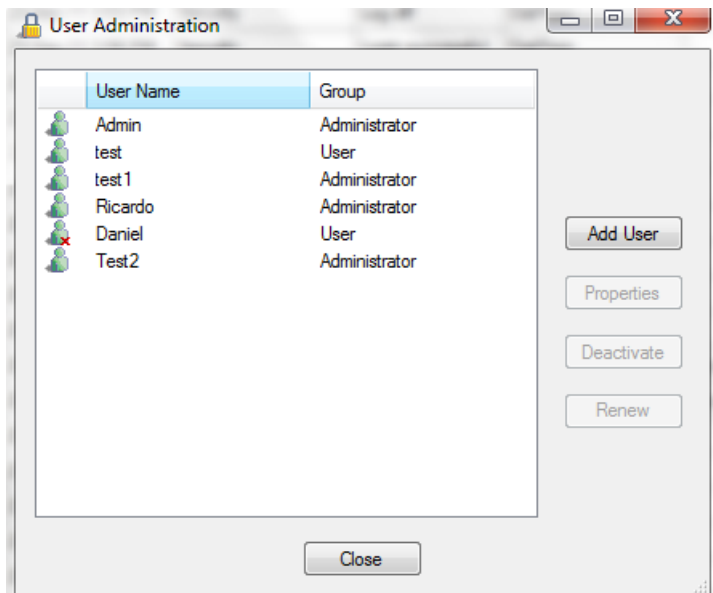
2. Click **Add User.**
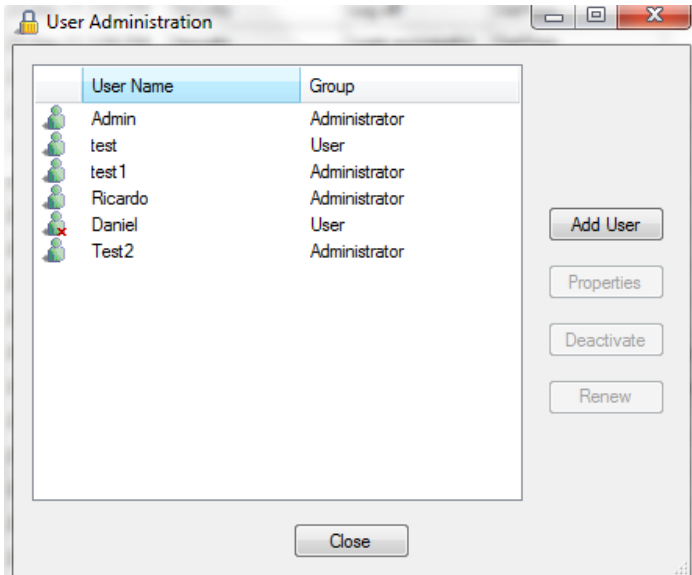
3. Enter a user name in the **User Name** text box.
4. Select a user group in the **Group** drop-down menu.
5. Set the login preferences in the **Login Settings** area.
6. Click **OK.**

Changing User Properties

1. Click **User Administration** on the main toolbar.

2. Select a user name from the list, then click **Properties**.
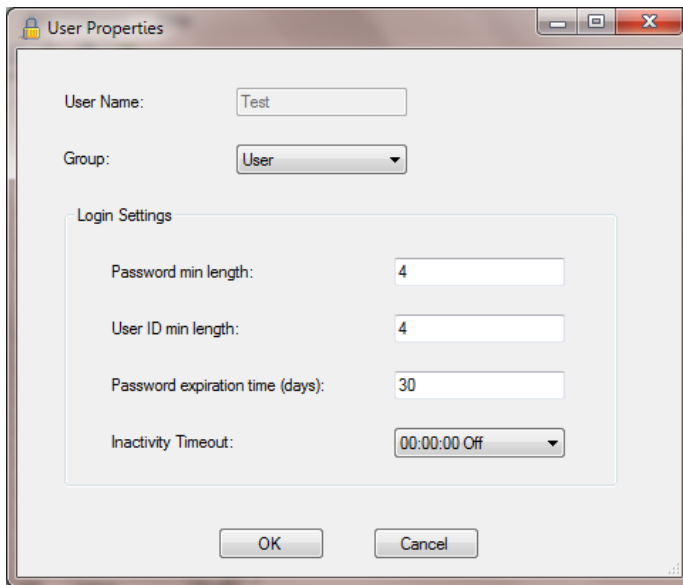
3. Modify the user group and/or the settings, and then click **OK.**

Deactivating a User

1. Click **User Administration** on the main toolbar.
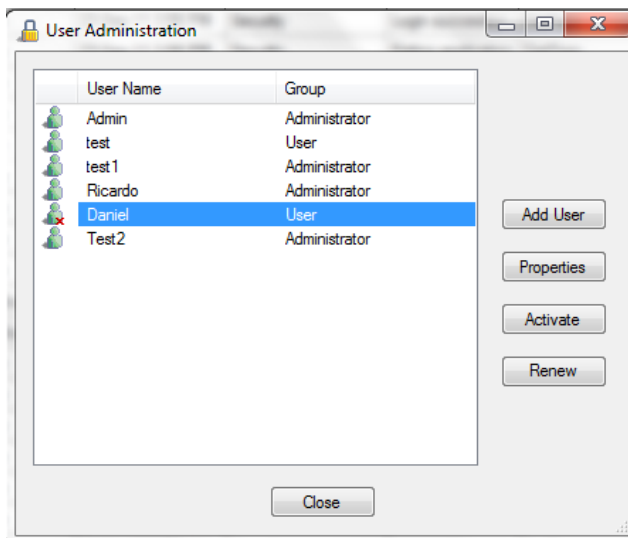
2. Select a user name from the list, and then click **Deactivate.**
   You can always reactivate the user by repeating the process, and then clicking **Activate**.

Changing Password

1. Click **User Administration** on the main toolbar.
2. Select a user name from the list, and then click **Renew Password.**
   The next time the user will open DatPass, he will be prompted to enter a new password.

Chapter 7.
Group Administration

Note: If are working in an archived audit trail (refer to Chapter 8 on page 21), then to access **Group Administration** you must first exit DatPass and login again to load the Current database.

Group Privileges
Users are assigned to user groups and are granted the privileges granted to the group. A privilege is a user's right to perform a specific task in DatPass, and supported fourtec software.
DatPass comes with three predefined user groups: **Administrator**, **Approver** and **User**. See the table below for the privileges granted to each group.

Privileges for DatPass

Privilege	Administrator	Approver	User
User Administration	✓		
View/Manage Audit Trail	✓		
Move Database	✓		

Privileges for DataSuite

Privilege	Administrator	Approver	User
File			
Open Data File	✓	✓	✓
Open Project File	✓	✓	✓
Save Project	✓	✓	✓
Save Project As	✓	✓	✓
Back Up System Files	✓	✓	✓
Restore System Files	✓	✓	✓
Print Map View	✓	✓	✓
Exit	✓	✓	✓
DataNet Network			
Refresh All Network Connections	✓	✓	✓
Show All Network Paths	✓	✓	✓
Tools			
Define Sensors	✓	✓	✓
Switch Sensor View Mode	✓	✓	✓
Lock Map View	✓	✓	✓
UTC Time Zone	✓	✓	
Email/SMS Alarm Notifications Setup	✓	✓	✓
Firmware Update Center	✓		
Device Detection			
Detect Device	✓	✓	✓
Stop All Devices	✓	✓	✓

Privilege	Administrator	Approver	User
Run All Devices	✓	✓	✓
Detect CoolTrak	✓	✓	✓
Reports			
Modify Report Profile	✓	✓	
Review Report	✓	✓	
Approve Report	✓		
Generate Report	✓		
Delete Report	✓		
Delete Profile	✓		
Data Export			
Export to Excel/CSV	✓	✓	✓
Print Data	✓	✓	✓
Copy Graph	✓	✓	✓
General			
Analysis Functions	✓	✓	✓
Modify Wallpaper	✓	✓	✓
Manage Contacts/Groups	✓	✓	
Mute/Unmute Software Alarm	✓	✓	✓
Change System Password	✓	✓	
Change Language Settings	✓	✓	
Software Registration	✓		
Check for Software Updates	✓	✓	
DataSuite Options Form	✓		

Device Privileges

Privilege	Administrator	Approver	User
DataNet Network Menu			
Lock Network	✓	✓	✓
Form New Network	✓		
Refresh Network Connections	✓	✓	✓
Show Network Path	✓	✓	✓
Mini DataNet Device Filter	✓		
Change to Substitute Receiver	✓	✓	✓
Change to Repeater	✓		
Change to Receiver	✓		
Device Menu			
Download Data	✓	✓	✓
Display Online Data	✓	✓	✓
Reset Alarm	✓	✓	✓
Call Device (Beep/Flash)	✓	✓	✓
Calibration	✓		
Firmware Update	✓		
Leave Network	✓		
Setup	✓	✓	✓
Alarm Setup	✓	✓	✓
Stop	✓	✓	✓

Privilege	Administrator	Approver	User
Cancel Download Data	✓	✓	✓
Run	✓	✓	✓
Show Network Path	✓	✓	✓
Change Short Range Repeater Mode	✓		
Signal Test	✓	✓	✓
Enable/Disable Turning Off Device	✓		
Remove	✓		
Turn Off	✓		
Multi-Setup	✓	✓	✓
Multi-Stop	✓	✓	✓
Multi-Run	✓	✓	✓

Privileges for DataNet

Privilege	Administrator	Approver	User
File			
Open Data File	✓	✓	✓
Open Project File	✓	✓	✓
Save Project	✓	✓	✓
Save Project As	✓	✓	✓
Exit DataNet	✓	✓	✓
Network			
Lock Network	✓	✓	✓
Form New Network	✓		
Refresh Network Paths	✓	✓	✓
Show Network Paths	✓	✓	✓
Device Filter	✓		
Tools			
Define Sensors	✓	✓	✓
Switch Sensor View Mode	✓	✓	✓
Edit Map View	✓	✓	✓
Alarm Notifications Setup	✓	✓	✓
Firmware Update Center	✓		
Reports			
Modify Report Profile	✓	✓	
Review Report	✓	✓	
Approve Report	✓		
Generate Report	✓		
Delete Report	✓		
Delete Profile	✓		
Data Export			
Export to Excel/CSV	✓	✓	✓
Print Data	✓	✓	✓
Copy Graph	✓	✓	✓
Device Menu			
Setup	✓	✓	✓
Logger Alarm Setup	✓	✓	✓
Calibration	✓		

Privilege	Administrator	Approver	User
Display Online Data	✓	✓	✓
Download Data	✓	✓	✓
Cancel Download Data	✓	✓	✓
Reset Alarm	✓	✓	✓
Call Device (Beep/Flash)	✓	✓	✓
Leave Network	✓		
Stop	✓	✓	✓
Run	✓	✓	✓
Show Network Path	✓	✓	✓
Change Short Range Repeater Mode	✓		
Signal Test	✓	✓	✓
Enable/Disable Turning Off Device	✓		
Remove	✓		
Turn Off			
Reset	✓		
Alarm Notifications Setup			
Modify SMS Alarm Settings	✓	✓	
Modify email Alarm Settings	✓	✓	
Manage Contacts/Groups	✓	✓	
General			
Firmware Update	✓		
Analysis Functions	✓	✓	✓
Modify Wallpaper	✓	✓	✓
Toggle Software Alarm	✓	✓	✓
Change System Password	✓	✓	
Check for Updates	✓		
DataNet Options Form	✓		

Privileges for MicroLab

Privilege	Administrator	Approver	User
Data			
New	✓	✓	✓
Open files	✓	✓	✓
Save files	✓	✓	✓
Save as	✓	✓	✓
User administration	✓		
View/Maintain Audit trail	✓		
Exit application	✓	✓	✓
Copy graph	✓	✓	✓
Crop data	✓	✓	✓
Export data to Excel	✓	✓	✓
Printout	✓	✓	✓
Update email settings	✓	✓	✓
Update store data folder	✓	✓	✓
Edit cradle map	✓	✓	✓

Privilege	Administrator	Approver	User
Data			
Set active cradle range	✓	✓	✓
Add electronic signature	✓	✓	
Logger Controls			
Communication setup	✓	✓	✓
Download	✓	✓	✓
Setup	✓	✓	✓
Run	✓	✓	✓
Stop	✓	✓	✓
Calibrate	✓		
Temp units	✓	✓	✓
Daily download software settings	✓	✓	✓
Define sensors	✓	✓	✓

The administrator can create a new user group and delete unused groups.

Changing Group Privileges

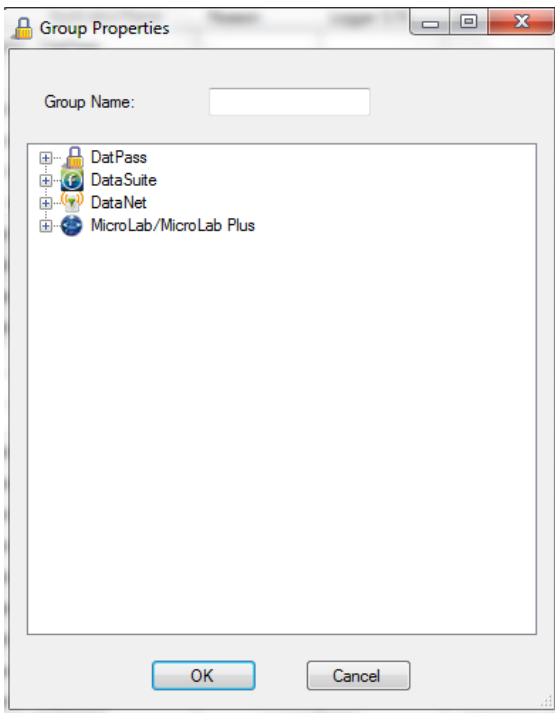1. Click **Group Administration** 👥 on the main toolbar.
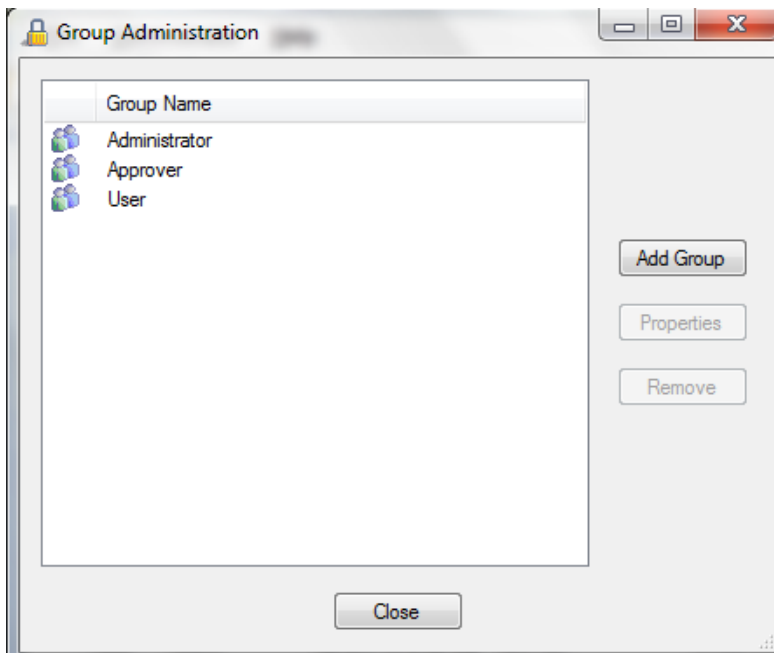
2. Click a group name to select it, and then click **Properties.**
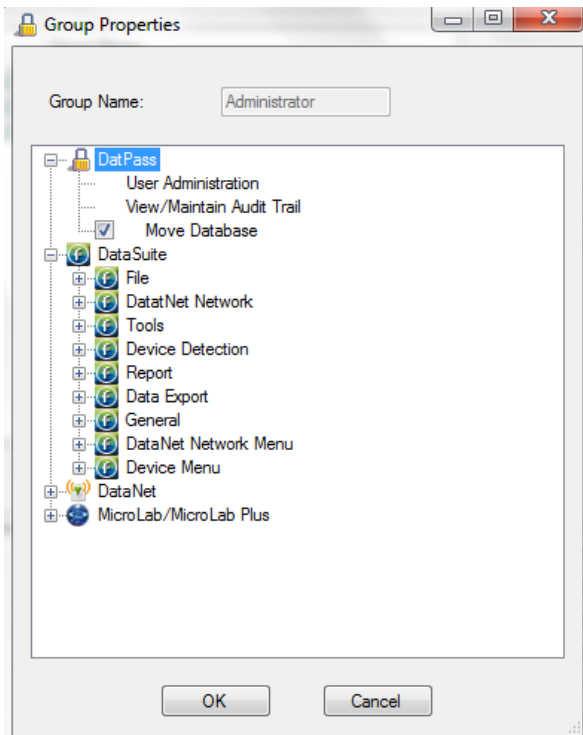
3. To add a privilege to the group, check the check box next to it.
4. To remove a privilege from the group, uncheck the check box next to it.
5. Click **OK**.

Adding a New Group of Users

1. Click **Group Administration** on the main toolbar.
2. Click **Add Group**.

3. Type in a group name in the **Group Name** text box.
4. To add a privilege to the group, check the check box next to it.
5. To remove a privilege from the group, uncheck the check box next to it.
6. Click **OK**.

Removing a User Group

1. Ensure that the group you want to remove is not assigned to any user.
2. Click **Group Administration** on the main toolbar.
3. Click the group name to select it, and then click **Remove Group.**
4. Click **Close**.

Chapter 8.
The Audit Trail

DatPass maintains an audit trail that automatically records any user activity within DatPass, and supported fourtec software.

The audit trail shows who has accessed the system and what operations he has performed, along with a date & time stamp of the activity. The audit trail also tracks invalid logins to the system.

The administrator can view the audit trail on screen or print any part of it. You can also copy any row of the trail to an Excel ® spreadsheet, for example.

DatPass allows you to create new audit trails while automatically saving the current trail.

Whenever a user uses a specific command such as **Run**, **Stop** or **Setup** for a device, from any of the supported software, the user is prompted to type a reason for his action. In such cases the audit trail records and displays the reason.

Printing the Audit Trail

1. Click **Print** 🖨 on the main toolbar.
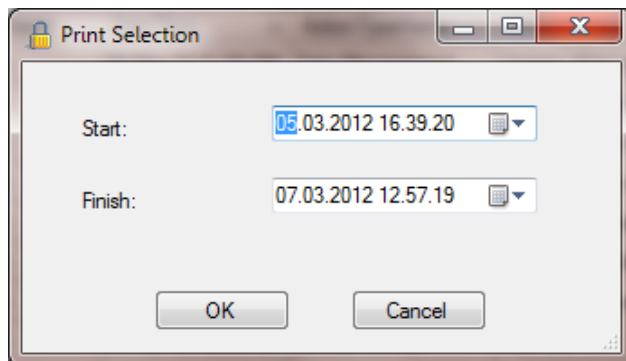
2. Select the start date and time in the **From** pick lists.
3. Select the end date and time in the **To** pick lists.
4. Select the page orientation.
5. Click **OK**.

Refreshing the Audit Trail

To refresh the audit trail display click **Refresh** 🔄 on the main toolbar. In addition, whenever the user logs in to DatPass, the audit trail is automatically refreshed.

Starting a New Audit Trail
Click **File** on the main menu, and then click **New.**
DatPass will automatically save the current audit trail, and open a new blank audit trail log.
DatPass saves the archived audit trail under the name: DatPass [date and time].

Note: You can only open a new audit trail when working in the Current database

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Opening an Old (Archived) Audit Trail

To open a previously used, archived audit trail follow these steps:

1. Click **Open** on the main DatPass toolbar.
2. Navigate to the folder where the archived database resided
   e.g. *My Documents\fourtec\DatPass*
3. Double click the desired file name.

Note: DatPass saves the audit trail under the name: DatPass [date and time]

To return to the current audit trail, repeat steps 1 and 2, then double click the file:
Current

Chapter 9.
Moving the Current Database

The Current.mdb file is by default located in the DatPass directory on your local computer. This file contains the current audit trail of user activity in the DatPass and support fourtec software systems.

When the Current database is located locally, it only tracks user activity on your computer. In order to maintain an audit trail of user activity over a network, rather than locally, you must store the DatPass Current.mdb file in a directory on the main network server to which the users are connected.

To move the database file in DatPass:

1. Click **Move Database** on the **File** menu.
2. In the **Set Database Path** dialog box, click **Browse** and browse to the new location of the database file.
3. Ensure that all supported software is closed and exit DatPass, then re-enter DatPass.
4. You will receive a system message confirming the database move, and you will also be able to view the action in the Audit Trail.

> **Note:** You will only be able to move the database if you have the Group privilege to do so. The **Move Database** check box must be checked in the **Group Properties** dialog box.

When the Current.mdb file has been moved using DatPass, the database path must also be updated for all supported software users on the network.

To correct the database file path in DataSuite, DataNet and MicroLab:
1. When logging into the software for the first time following a database move, you will see a system message stating that the database file was not found.
In the next dialog box, enter the default system password (refer to the
   Move Database Password section below) and click **Browse**.
2. Browse to the new path of the database file, as defined in DatPass, and click **OK**.
3. Login in to the software as you normally would.

The DatPass Admin will now be able to view the audit trail of all users of the DataSuite, DataNet and MicroLab software on the network.

Move Database Password
The default password for DataSuite users is:
fourteccfr

The default password for DataNet and MicroLab is:
fouriersystems

This password is case sensitive and cannot be changed.