

DatPass

Compliant with FDA Title 21 CFR Part 11 and GAMP 4



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User Guide

DatPass v2.0 User Guide

FDA 21 CFR Part 11 Compliant

**Supporting DataNet and MicroLab
Software**

May 2010

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fourier

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Introduction

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

DatPass works with the following Fourier Systems software:

- DataNet – supporting DataNet data loggers, Receiver and Repeater
- MicroLab – supporting MicroLog and MicroLog PRO 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 DataNet, MicroLab, and MicroLab Lite, DatPass forms a dual program software package that complies with FDA Title 21 CFR Part 11.

Associated Documentation

- DataNet v2.0 for CFR User Guide
- MicroLab for CFR User Guide
- DatPass and DataNet CFR Validation Manuals
- DatPass and MicroLab CFR Validation Manuals

Installing DatPass

System requirements

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

Software

- Windows 98, 2000, XP, Vista or Windows 7
- Internet Explorer 4.0, or later

Hardware

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

Installing the software


<p>Note: Do not connect the USB Security dongle to the PC until the installation is complete</p>

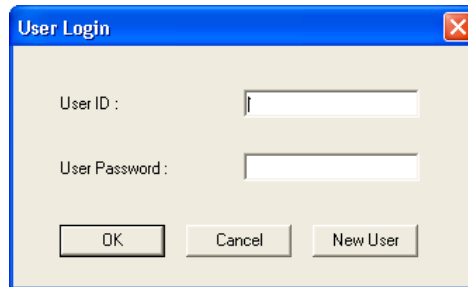
1. Insert the DatPass CD into your CD drive.
2. Enter the DatPass folder on the CD and click the setup.exe file.
3. The DatPass software installation process will begin. The USB Security dongle HASP device drivers will first be installed. Upon completion, the message *The operation was successfully completely* will be displayed. Click **OK** to continue to the next stage of the DatPass installation.
4. Follow the on-screen instructions to complete the DatPass installation.
5. Once the installation is complete, you may then connect the USB Security dongle to the PC. The dongle will be automatically recognized as new hardware by the PC.

First Time Running DatPass

Note: DatPass will not run unless the USB Security dongle is connected to the PC

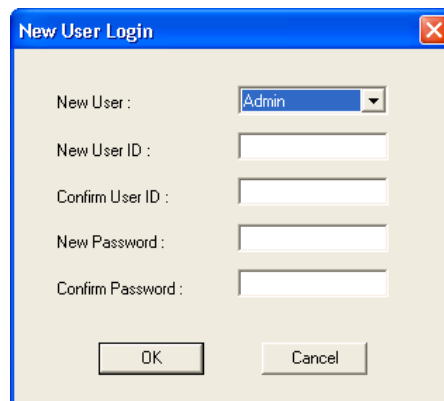
The first user that opens DatPass is automatically assigned as an Administrator and is given the user name Admin. To start working with DatPass the administrator needs to define his own user ID and password:

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



The 'User Login' dialog box has a blue title bar with the text 'User Login' and a close button (X). It contains two text input fields: 'User ID :' and 'User Password :'. Below the fields are three buttons: 'OK', 'Cancel', and 'New User'.

2. Click **New User**.



The 'New User Login' dialog box has a blue title bar with the text 'New User Login' and a close button (X). It contains a dropdown menu for 'New User :', which is currently set to 'Admin'. Below this are four text input fields: 'New User ID :', 'Confirm User ID :', 'New Password :', and 'Confirm Password :'. At the bottom are two buttons: 'OK' and 'Cancel'.

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

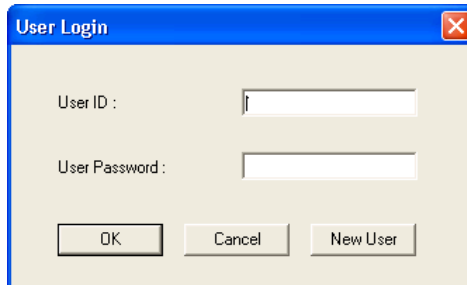
6. Confirm the password in the **Confirm Password** text box.
7. Click **OK**.

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

Login to DatPass

Old User

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




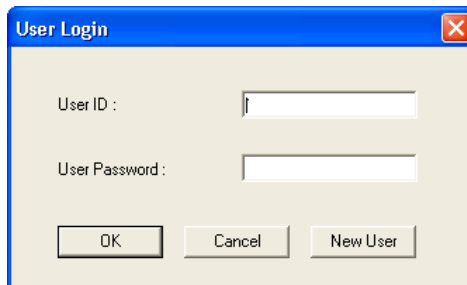
The 'User Login' dialog box has a blue title bar with the text 'User Login' and a close button (X). It contains two text input fields: 'User ID :' and 'User Password :'. Below the fields are three buttons: 'OK', 'Cancel', and 'New User'.

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

New User

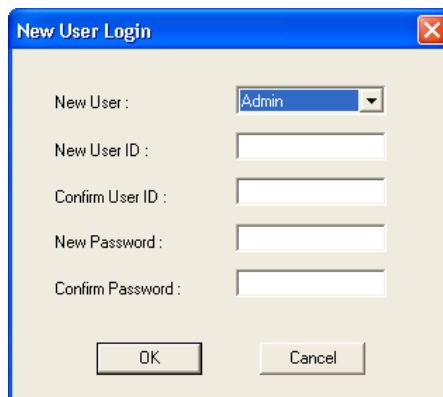
You can only login as a new user to DatPass and supported Fourier software if the Admin has created a new user in DatPass. Refer to the *Adding a New User* section on page 6.

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



The 'User Login' dialog box is identical to the one shown in the previous section, with fields for 'User ID' and 'User Password' and buttons for 'OK', 'Cancel', and 'New User'.

2. Click **New User**.



The 'New User Login' dialog box has a blue title bar with the text 'New User Login' and a close button (X). It contains a dropdown menu for 'New User' (currently showing 'Admin'), and four text input fields: 'New User ID :', 'Confirm User ID :', 'New Password :', and 'Confirm Password :'. At the bottom are 'OK' and 'Cancel' buttons.

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**.

User Administration

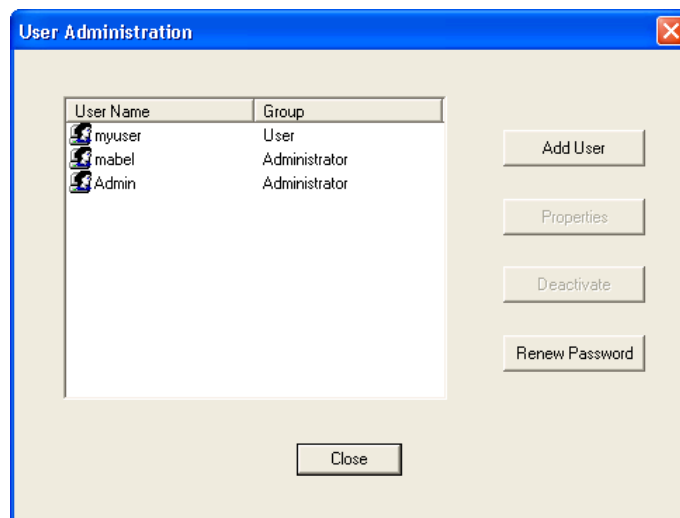
Note: If are working in an archived audit trail (refer to page 14), then to access **User Administration** you must first exit DatPass and login again to load the Current database.

Adding a User

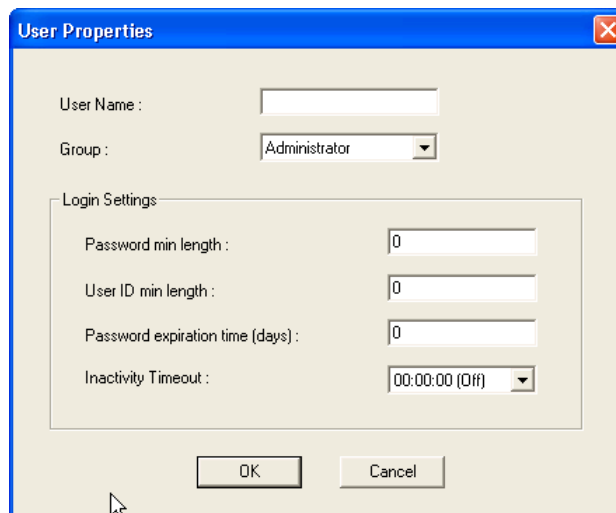
An administrator can add new users, assign privileges to the user and set the login preferences.

To add a new user:

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



2. Click **Add User**.

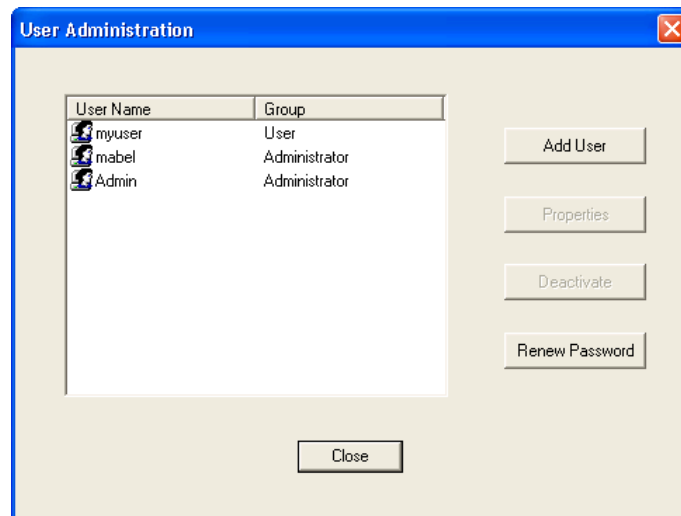


3. Enter a user name in the **User Name** text box.
4. Select a user group in the **Group** drop-down menu.
5. Set the login preferences in the **Login Settings** area.
6. Click **OK**.

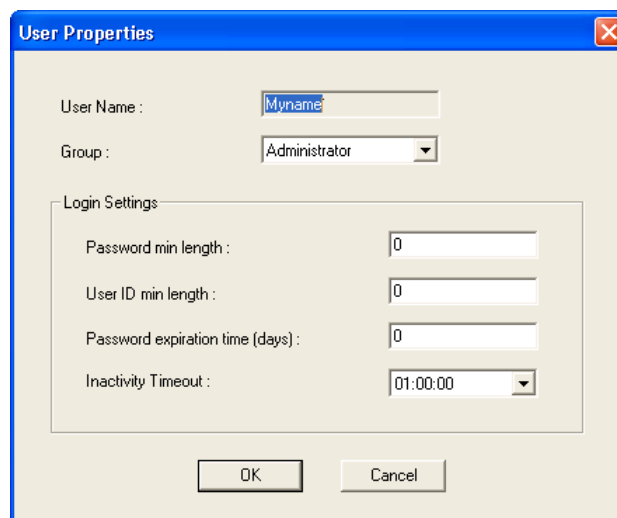
Changing User Properties



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



2. Select a user name from the list, then click **Properties**.

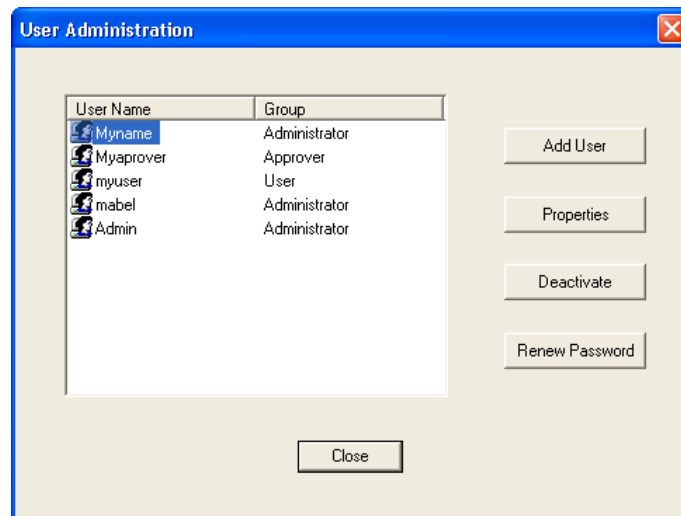


3. Modify the user group and/or the settings, and then click **OK**.

Deactivating a User



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

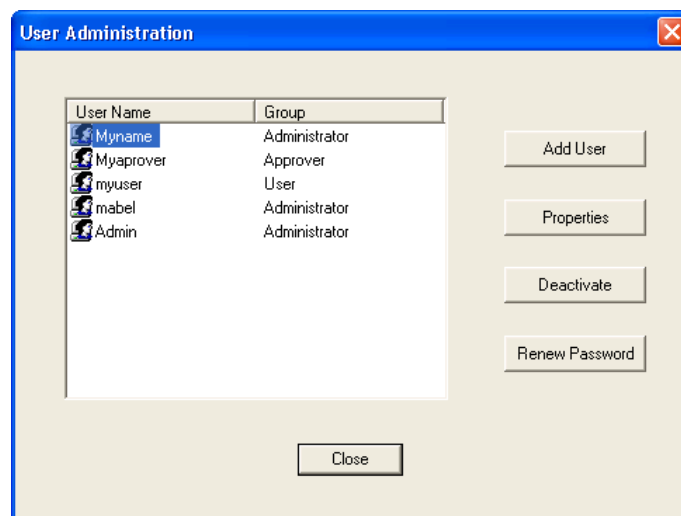


2. Select a user name from the list, and then click **Deactivate**.
You can always reactivate the user by repeating the process, and then clicking **Activate**.

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.

Group Administration

Note: If are working in an archived audit trail (refer to page 14), 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 Fourier 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 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	✓	✓	✓

Privilege	Administrator	Approver	User
Logger Alarm Setup	✓	✓	✓
Calibration	✓		
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

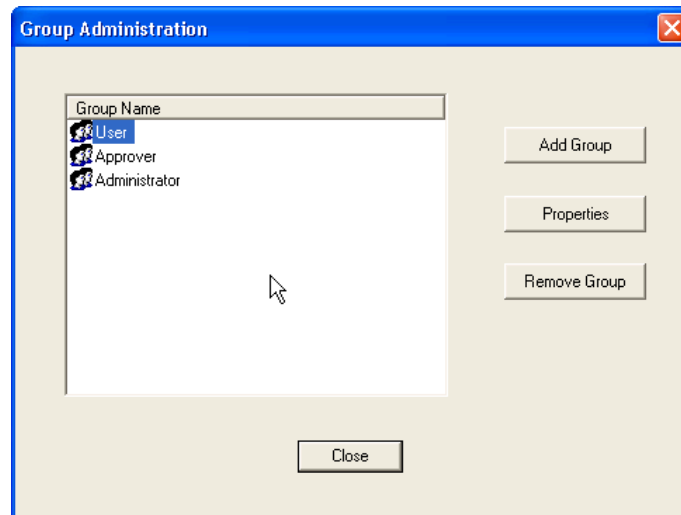
Privilege	Administrator	Approver	User
Data			
New	✓	✓	✓
Open files	✓	✓	✓
Save files	✓	✓	✓
Save as	✓	✓	✓
User administration	✓		
View/Maintain Audit trail	✓		
Exit application	✓	✓	✓
Copy graph	✓	✓	✓
Crop data	✓	✓	✓
Export data to Excel	✓	✓	✓
Printout	✓	✓	✓
Update email settings	✓	✓	✓
Update store data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

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

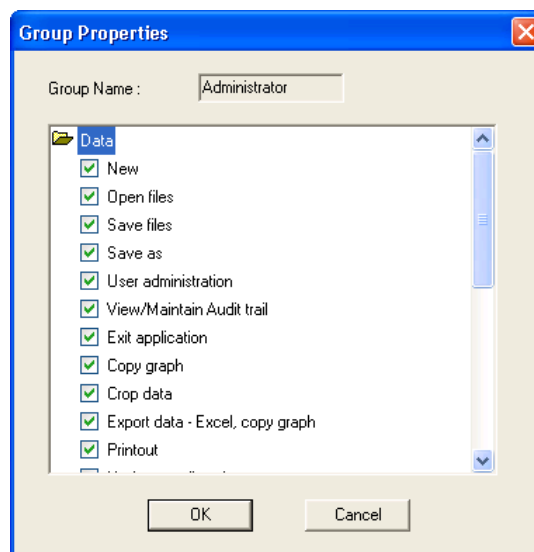
The administrator can create a new user group and delete unused groups.

Changing Group Privileges

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



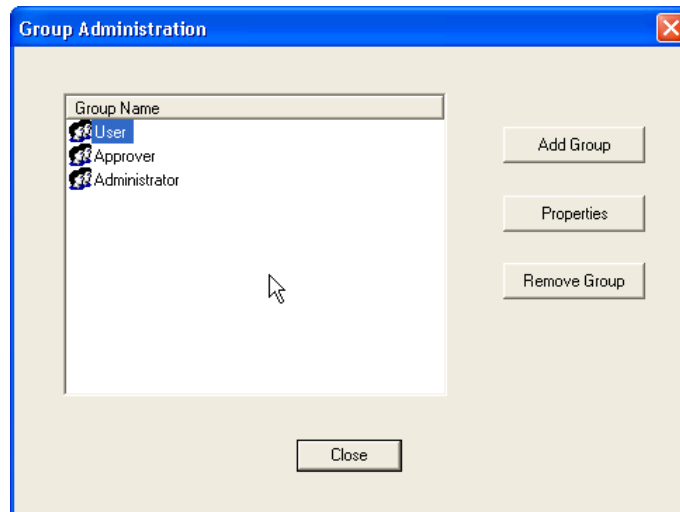
2. Click a group name to select it, and then click **Properties**.



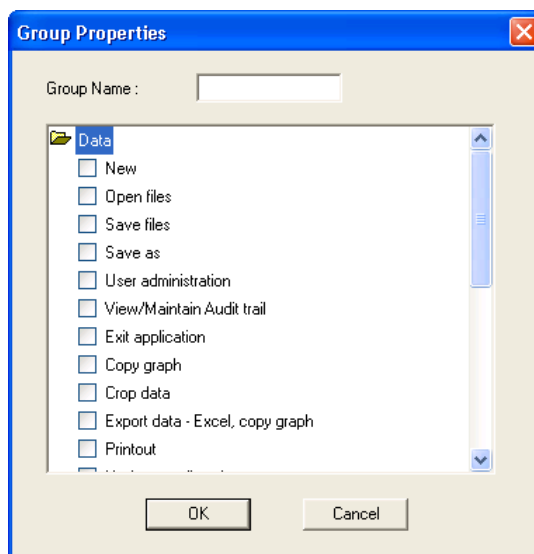
3. To add a privilege to the group, check the check box next to it.
4. To remove a privilege from the group, uncheck the check box next to it.
5. Click **OK**.

Adding a New Group of Users

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



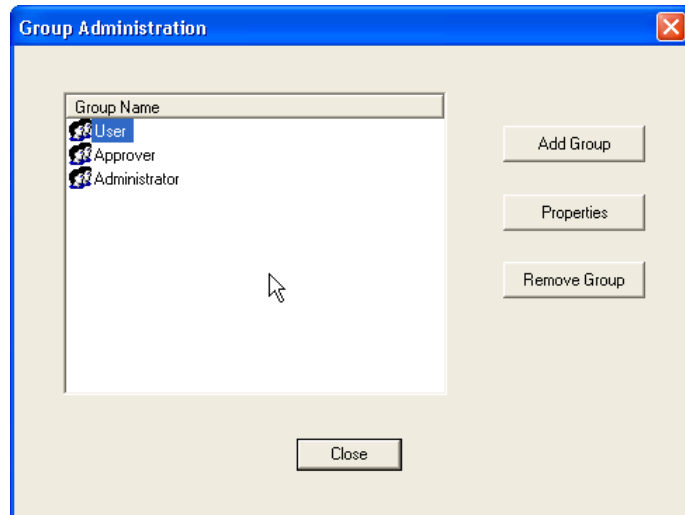
2. Click **Add Group**.



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**.

Audit Trail

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

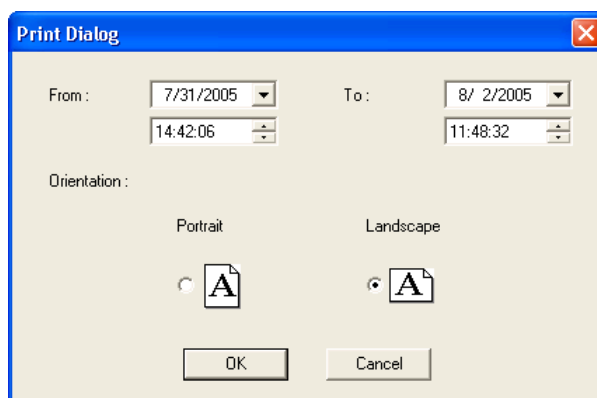
The administrator can view the audit trail on screen or print any part of it.

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.

Viewing a Specific Date

To view audit trail entries on a specific date:

1. Click the down arrow next to the date drop-down list  on the main toolbar.
2. Select the desired date.
The display will automatically scroll to the selected date.

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

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

Opening an Old Audit Trail

1. Click **Open**  on the main toolbar.
2. Navigate to the folder: *My Documents\Fourier Systems\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

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 Fourier 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 DataNet and MicroLab 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 should receive a system message confirming the database move, and you should 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 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 DataNet and MicroLab software on the network.

Move Database Password

The default password allowing users of DataNet and MicroLab to correct the database file path once it has been moved is:

fouriersystems

This password is case sensitive and cannot be changed.