# **Feature Database Manager**

LabSpeed User Management and Security

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## **Feature Database Manager Overview**

Feature Database Manager is a LabSpeed Feature add-in that provides SQL Server database support for the following LabSpeed security options

- User Management using Windows login credentials for verification
- Permission Groups for Administrator, Power User and User user types
- Individualized User Permissions
- 21-CFR Part 11 Compliance
- Journal

An Administrator can setup the security environment for LabSpeed to control how users in the lab will interact with LabSpeed and optionally force compliance with 21-CFR Part 11 regulations.

Two new top level LabSpeed menu items are added when the Feature Database Manager is active:

	Admin
	System Options
User	Manage Users
Log in	Assign User Permissions
Log out	Setup User Groups
Make a Journal Entry	Journal
• •	

User Menu

Admin Menu

### **Summary of Security Features**

- The User menu allows a user to log in and log out. The Admin Menu provides access to Options, User and Permission management and the Journal. System Options is where an administrator will enable Permissions and 21-CFR Part 11 compliance. By default, they are turned OFF.
- There is a default administrator user. Username = "Administrator", Password = "Administrator". Log on as the default administrator user to access the Admin menu items. It may be disabled later once other administrator users are assigned.

- All assigned Users must have active Windows log-in credentials. When a user logs into LabSpeed, his Windows log-in credentials are tested; if they pass, then the user is logged in.
- Users may be assigned a Permission Group -- "Administrator", "Power User" or "User". "Administrator" users always have all permissions. You can choose how the "Power User" and "User" groups are setup and what options will be available to each.
- Individual users can be assigned Permissions that are allowed for his/her group. When a new user is added, all permissions are off for that user by default. You will have to turn on some or all permissions for each added user.
- When the 21-CFR P11 Option is turned ON, a User must be 21-CFR Compliant in order to log into LabSpeed. A user is 21-CFR compliant if there is a Full Name associated with his LabSpeed user credentials.
- When a user logs in, actions that are not allowed will be disabled in the toolbar and menus. When no-one is logged in, all permission actions are disabled.
- The Journal tracks changes to Permissions and Options.
- A Special 21-CFR Signature View may be added to any Session/Template (drop down the Special Views toolbar button). Multiple selected samples or experiments may be signed at the same time.
- A report may contain the full name of the logged-in user.
- A journal is maintained to keep track of option and permissions settings and users who log in and log out.
- If a Service is employed to automatically transfer saved data to the Topos SQL Server database, it may be setup to participate in the user permissions and 21-CFR authoring of samples and experiments.

# **System Options**

To access the System Options, you must be logged in as an Administrator. Before any users are added, including administrators, you can log in using the default Administrator user name and password. This user can be used initially until an actual Administrator and password are added and can then be disabled for security.

#### **Default Administrator User Credentials**

Username = "Administrator" Password = "Administrator"

Click on the Admin->System Options menu item. The following dialog is displayed:



Initially, all options are disabled (unchecked). When disabled, LabSpeed runs without users and permissions as if the Feature Database Manager was not installed.

#### **Enabling User Permissions**

When User Permissions is enabled, users are required to login in order to use LabSpeed. Any action a user is denied, based on the assigned Permissions for that user, will be disabled in the menus and toolbar.

#### **Enabling 21-CFR Part 11 Compliance**

When 21-CFR Part 11 compliance is enabled, User Permissions is also enabled and forced on.

When 21-CFR Part 11 compliance is enabled, only users who are 21-CFR P11 compliant may log on and participate in using LabSpeed. Compliance for 21-CFR Part

11 is determined by the user's LabSpeed credentials. A user with a valid Full Name (first and last) is considered 21-CFR Part 11 compliant. See <u>Managing Users</u>

#### Enabling User Lockout after maximum failed log in attempts

When User Permissions is enabled, users are required to login in order to use LabSpeed. The Log in window will automatically exit after a maximum of three (3) failed log in attempts. The Log in window will have to be re-opened to try again. If lockout is enabled and the same user attempted and failed three times to log in, the user will be de-activated. An Administrator is required to re-activate the user. See <u>Managing Users</u>

# Logging In / Out

When User Permissions are <u>enabled</u>, a user is required to login to use LabSpeed. To login, go to the *User Menu* and choose *Log In*.

User	
l	.og in
l	.og out

The following dialog is displayed:

S F K	
Domain	
David-THINK	<u> </u>
User Name	
Password	
Log In	
Log In	

Enter your Windows login credentials.

A Maximum of three (3) attempts is allowed before failing to login. You will need to exit and re-enter to try again. If the administrator option is set to lock out the user after three attempts is turned on, the user will be de-activated. An administrator is required to reactivate the user.

Once logged in successfully, the menus and toolbar items are enabled to conform to the user's assigned permissions.

A new user may login without logging out the previous user.

When no one is logged in (at startup and when user logs out), all actions that require a permission are disabled.

# **Managing Users**

To manage users, you must be logged in as an Administrator.

Click on the Admin->Manage Users menu item. The following dialog is displayed:

			User l	List		
Active	User Name	Group Member	Full Name	21-CFR Part 11 Compliant	Date Created	Date Modified
<b>V</b>	Administrator	Administrator	Administrator Default	True	4/05/2013 11:34:52	4/08/2013 12:41:52
0 🔽	David	Administrator	David Galligan	True	4/15/2013 15:44:21	4/15/2013 15:44:21
	Mary	Power User	Mary Costello	True	4/17/2013 04:00:04	4/17/2013 04:00:04
	Jdp	User	John Parillo	True	4/17/2013 04:05:04	4/17/2013 04:05:04

The first entry is the default Administrator. It may be de-activated and activated at any time by an Administrator. Typically, once other Administrators have been added, the default Administrator is de-activated for security, since the password is public.

### **Creating a New User**

Click on New User to add a new user to the list. The following dialog is displayed:

Domain :	David-THINK	-
Log on Username	: jdp	
User's full name :	John Parillo	
Group Member :	User	
21 CFR Part 11 Co	mpliant = True	

<u>The user's username must be a valid Windows username with Windows user</u> <u>account.</u> In LabSpeed, when someone logs on, the Windows credentials (domain, username and password) are tested. If it passes, then the user will successfully log into LabSpeed. Note that Windows accounts maintain password aging and other criteria important for 21-CFR Part 11 compliance. If a user does not have a Windows account, he/she will not be able to log into LabSpeed.

The user's full name is required for 21-CFR Part 11 compliance. If the user does not have a full name, and 21-CFR P11 compliance is enabled in <u>System Options</u>, then he will not be allowed to log into LabSpeed.

The Group Member is the user's group type -- Administrator, Power User or User. See <u>Permission Groups</u>

Once a new user is added to the list, parts of it may be edited in the table row.

Active User Name Group Member Full Name 21-CFR Part 11 Compliant Date Created Date   Image: Administrator Administrator Administrator Default True 4/05/2013 11:34:52 4/08/2013   Image: Administrator David Administrator David Galligan True 4/15/2013 15:44:21 4/15/2013   Image: Administrator Power User Mary Costello True 4/17/2013 04:00:04 4/17/2013   Image: Administrator John Parillo True 4/17/2013 04:05:04 4/17/2013	10000				0001					
Image: Administrator     Administrator     Administrator Default     True     4/05/2013 11:34:52     4/08/20       Image: Administrator     David     Administrator     David Galligan     True     4/15/2013 15:44:21     4/15/20       Image: Administrator     David Galligan     True     4/17/2013 04:00:04     4/17/20       Image: Administrator     Power User     Mary Costello     True     4/17/2013 04:00:04     4/17/20       Image: Administrator     Jdp     User     Image: John Parillo     True     4/17/2013 04:05:04     4/17/2013 04:05:04	ate Modified	ated	Date Creat	21-CFR Part 11 Compliant	Full Name	er	Group Member	User Name	ctive	A
Image: Weight of the second	2013 12:41:52	:34:52	4/05/2013 11:3	True	Administrator Default		Administrator	Administrator	V	
Image: Mary     Power User     Mary Costello     True     4/17/2013 04:00:04     4/17/	2013 15: <mark>44</mark> :21	:44:21	4/15/2013 15:4	True	David Galligan		Administrator	David		
Jdp User John Parillo True 4/17/2013 04:05:04 4/17/20	2013 04:00:04	:00:04	4/17/2013 04:0	True	Mary Costello	-	Power User	Mary	V	
Administrator	2013 04:05:04	:05:04	4/17/2013 04:0	True	John Parillo	•	User	Jdp	1	
PowerUser User			1		}	6	Administrator PowerUser User	4		

The Group Member, Full Name and Active State may be changed. Note that the User Name may not be changed. To change a user name, that user may only be deactivated and re-added again.

### **De-activating a User**

A user may not be deleted. He can only be de-activated, e.g. should a user leave the company or if the user is no longer a valid user. To de-activate a user, un-check the Active state for that user. A user may be re-activated by checking the Active state on.

# **Assigning User Permissions**

To assign permissions to individual users, you must be logged in and have permission. An administrator always has permission.

Every user has been assigned a <u>User Group</u> (*Administrator*, *Power User* and *User*), which defines the range of permissions allowed for each user. An administrator may then customize those permissions for each individual user. For example, one member who is a *Power User* may be allowed to sign samples and another may not.

Click on the *Admin->Assign User Permissions* menu item. The following dialog is displayed:

ser Na	me:	John Parillo (User)		
	Mary			
Allow	Category	Uption 2		
	Service	Stop File Monitor Service		
1	Session	Create a New Session		
	Session	Modify and Save Session Templates		
	Session	Create and Edit Connections		
V	Session	Stop Monitor		
Session		Append Data		
Session		Edit Refresh Settings		
Session     In       Image: Session     A		Import and Export Sessions		
		Add and Remove Views		
	View	Create Charts		
	View	Create Tables		
	View	Create Research Grids		
	View	Create Reports		
	View	Create User Tables		
	View	Edit Views in Designer Mode		
V	View	Save Views		
	1.1.01			

Select a user to modify in the drop down list. A list of available permissions is presented for that user (this displayed list will depend on the User Group that user is assigned to). Toggle on/off permissions allowed for that user to customize the permission set for that user.

In the example above, the user *Jdp* is assigned simple operating rights and is not allowed to create new Charts, Tables, Research Grids and Reports and not allowed to modify existing ones using the View Designer.

The tab shows the current Application name. Additional tabs may appear depending upon other sources that may require assigned permissions.

Click Save and Close to save the changes.

# **Setting up User Groups**

To setup User Groups, you must be logged in and have permission. An administrator always has permission.

There are 3 types of users

- 1. Administrator
- 2. Power User
- 3. User

Each user that uses LabSpeed is assigned a User Group. The User Group defines the range of permissions allowed for users in that Group.

Since the Administrator always has all permissions, only the *Power User* and *User* groups may be setup. How the administrator decides to operate the lab will determine the settings in each group. For example, a *User* may be considered an instrument operator with few rights to change anything. a *Power User* may have almost all the permissions of an administrator, or he may be allowed only *User* rights plus additional modification rights, such as changing and editing Templates and Views. It is up to the Administrator.

A user's permission set may be further customized when setting <u>individual user</u> <u>permissions</u> that will be a subset of the permissions allowed by his Group.

Click on the Admin->Setup User Groups menu item. The following dialog is displayed:

Current User Group Member	David Administrator			Show Short Option I
Category	Option	PowerUser Group	User Group	Date Modified
Advanced	Manage Clients			4/08/2013 14:44:36
Advanced	Edit Settings			4/08/2013 14:44:36
Advanced	Activate Feature Options			4/08/2013 14:44:36
Advanced	Manage License			4/08/2013 14:44:36
Advanced	Assign User Permissions			4/17/2013 18:05:05
Advanced	Setup User Groups	Ì		4/08/2013 14:44:36
Advanced	View Journal			4/08/2013 14:44:36
Advanced	Sign Samples and Experiments			4/08/2013 14:44:36
Service	Stop File Monitor Service			4/08/2013 14:44:36
Service	Edit File Monitor Service Settings			4/08/2013 14:44:36
Service	Edit File Monitor Service Admin Options			4/08/2013 14:44:36
Session	Create a New Session	<b>V</b>	<b>V</b>	4/08/2013 14:44:36
Session	Lock and Unlock Session			4/08/2013 14:44:36
Session	Modify and Save Session Templates			4/08/2013 14:44:36
Session	Create and Edit Connections			4/08/2013 14:44:36
Session	Stop Monitor			4/08/2013 14:44:36
Session	Append Data			4/08/2013 14:44:36
Session	Edit Refresh Settings			4/08/2013 14:44:36
Session	Import and Export Sessions			4/08/2013 14:44:36
Session	Add and Remove Views	<b>V</b> .	<b>V</b>	4/08/2013 14:44:36
Template	Create and Edit Templates			4/08/2013 14:44:36
View	Create Charts			4/08/2013 14:44:36
View	Create Tables	<b>V</b>		4/08/2013 14:44:36
View	Create Research Grids	<b>V</b>		4/08/2013 14:44:36
View	Create Reports	<b>V</b>		4/08/2013 14:44:36
View	Create User Tables		V	4/08/2013 14:44:36
View	Edit Views in Designer Mode		<b>V</b>	4/08/2013 14:44:36
√iew	Save Views	<b>V</b>	<b>V</b>	4/08/2013 14:44:36

The above list represents all of the permissions that may be assigned to each user when logged into LabSpeed. Permissions come in five (5) organizational categories -- Advanced, Service, Session, Template and View. Note in the example above the *Power User* has many of the rights of the Administrator except a few, which include managing the LabSpeed license and modifying Users. The *User* is given fewer rights. The Administrator may give the *User* even fewer rights, e.g. to not allow creating and changing charts and tables. The rights for each group will be setup for how the Administrator will want to run the lab.

Note: If a *Power User* has permission to edit the permission groups, he/she is not allowed to change the permissions for his own group. For example, if a *Power User* is given permission by the Administrator to setup user groups, the *Power User* will only be able to change the Group settings for the *User* group.

# **Viewing the Journal**

A journal is maintained to keep track of who is running LabSpeed and any changes to his/her status.

#### in LabSpeed

- When LabSpeed is started and closed
- When someone logs on or off
- When a User Group changes and what the changes are
- When permissions for a user changes and what the changes are
- When System Options are changed and what the changes are
- When Monitor is started or stopped
- When a Monitor status error occurs

In the File Monitor Service (if one is employed)

- When a Service Starts or Stops
- When the Service Options are changed and what the changes are
- When Service Settings are modified
- When 21-CFR P11 Authoring is enabled, and the operator cancels or fails to sign

Click on the *Admin->Journal* menu item. The following dialog is displayed:

(i) 4/	17/2013 06:05:05 PM	Denid				1
		David	LabSpeed LS	LabSpeed_LS_1	Permission Group Changed	
· 🖓 🖑	17/2013 06:04:07 PM	David	LabSpeed LS	LabSpeed_LS_1	User Permission Changed	(Jdp)Session Create
4/	17/2013 06:02:38 PM	David	LabSpeed LS	LabSpeed_LS_1	User Permission Changed	(Jdp)Service:Stop Fi
4/	17/2013 06:02:04 PM	David	LabSpeed LS	LabSpeed_LS_1	User(s) Added or Modified	
(i) 4/	17/2013 06:01:56 PM	David	LabSpeed LS	LabSpeed_LS_1	User(s) Added or Modified	
(i) 4/	17/2013 06:01:10 PM	David	LabSpeed LS	LabSpeed_LS_1	User Logged In	
<b>(i)</b> 4/	17/2013 06:00:27 PM	David	LabSpeed LS	LabSpeed_LS_1	User(s) Added or Modified	
(i) 4/	17/2013 05:58:35 PM	David	LabSpeed LS	LabSpeed_LS_1	User(s) Added or Modified	
(i) 4/	17/2013 05:37:31 PM	David	LabSpeed LS	LabSpeed_LS_1	User Logged In	
(i) 4/	17/2013 05:35:53 PM		LabSpeed LS	LabSpeed_LS_1	LabSpeed LS Started	
i) 4/	17/2013 09:36:59 AM		SoftMaxServiceCon	CtlrTEST3	Service Stopped	
<li>(i) 4/</li>	17/2013 09:31:29 AM		SoftMaxServiceCon	CtlrTEST3	Service Started	

Each Journal entry shows the following

- DateTime when the entry occurred
- User Name who was logged on
- Application application name identifies the source of the journal entry
- Instance Name identifies the unique instance of the application, service or addin if multiple instances are being run over a network
- Description journal entry description
- Details additional details, which may include what changed

Select a particular entry to show the Details in the box at the bottom. In the example above, the Journal entry indicates User Permissions changed and the details indicate what those changes were and for whom (Jdp).

### To view journal entries for a different date range

By default, the Journal Viewer displays entries for the current day. To view journal entries for more days, set the value for #days and click **Search**. To specify a particular date range, click on **Custom**, set the date range required (From and To) and click **Search**.

C # Days	From	4/19/2013	•	Search
Custom	To	4/19/2013	•	

### To filter journal entries to view a subset of entries

You can filter the list by User Name, Application, Instance Name and Description. Click on the "funnel" icon in the column header. A drop down list of acceptable column items is displayed for selection. You can also create a custom filter with wildcards and script logic. For example, if you filter on the Description column for "User Edit" or "Manual Journal Entry", only those entries will be displayed. Filters on multiple columns may be applied.

## **Adding a Manual Journal Entry**

If the user has permission, a manual journal entry may be entered at any time. The entry is tagged by user name and date and is easily reviewed later in the <u>Journal</u> <u>Viewer</u>.

Click on the User->Make a Journal Entry menu item.

User	
	Log in
	Log out
	Make a Journal Entry

The following dialog is displayed:

ournal Entry - David		X
Make an entry in the journal		
This is an example journal entr	y]	
	ОК	Cancel

Enter any text, notes or facts and click OK.

You can view all manual journal entries in the <u>Journal Viewer</u> by filtering on "Manual Journal Entry" in the Description column.

# **Signing Samples and Experiments**

Feature Database Manager provides a special View for signing samples and experiments as *Author*, *Approved*, *Reviewed* and *Verified*. The 21CFR-P11 Signature View may be added to any Session and saved with that Session's template.

LabSpeed LS (Admin) - MolecularDevices	SoftMax	:DB - Sign S	Samples							- 0 ×
Session View Client Tools Admin U	ser Hel	р								
🔁 🗟 🚨 🛅 🗔		12 🧧		کې 😔		TT 📊 🔚 🛛	2 🐔 🗗			
Sign Samples A   21CER-P11 Signature View1	Add S	<b>J</b> Signature	Data 27.b 3/8/2013 11:0	tt 7:25 AM						
	DateT	ime	User Na	ime	Full Name		Reason	Comments	5	
	4/17/2	013 6:15:45	PM David		David Galliga	n	Author	Samples r	an under Spec	#554
	4/17/20	013 6:36:24	PM Admin		Martin Campb	ell	Approved			
						Research Grid				
	Drag a	column he	ader here to grou	p by that co	lumn.					
	Si	gned 🏹	Filename V	FileRe	adType 5	7 FilePath	FileDateTime	e V	Identifier	▼ ExplD ▼
	<b>.</b>		Data 03-05-13-15	Endpoint_E	хр	C:\ProgramData\Molec	J 3/5/2013 3:18:13	PM C	thrTEST	38
	÷		Data 21.txt	Endpoint_E		C.\Program Files (x86)	3/8/2013 9:45:49	AM C	thTEST	39
			Data 22.txt	Endpoint_E		C.\Program Files (x86)	3/8/2013 9:54:04	AM C	thrTEST	40
	÷		Data 23.txt	Endpoint_E		C.\Program Files (x86)	3/8/2013 10:22:19	9 AM C	tirTEST	41
			Data 26.txt	Endpoint_E		C:\Program Files (x86)	3/8/2013 10:28:02	2 AM C	thrTEST	42
	⊕ ►		Data 27.txt	Endpoint_E		C.\Program Files (x86)	3/8/2013 11:07:25	5 AM C	thrTEST	43
	÷		Data 28.txt	Endpoint_B	хр	C:\Program Files (x86)	3/8/2013 12:00:32	2 PM C	tirTEST	44
	+		Data 30.txt	Endpoint_E	xp	C:\Program Files (x86)	3/8/2013 12:03:37	7 PM C	tirTEST	45
	+		Data 31.txt	Endpoint_B	хр	C:\Program Files (x86)	3/8/2013 12:05:23	3 PM C	tirTEST	46
	+	Г	Data 32.txt	Endpoint_B	хр	C:\Program Files (x86)	3/8/2013 2:39:51	PM C	tirTEST	47
	÷.		Data 33.txt	Endpoint_E	хр	C:\Program Files (x86)	3/8/2013 2:41:46	PM C	tirTEST	48
	+		Data 34.txt	Endpoint_E	Бхр	C:\Program Files (x86)	3/8/2013 2:45:14	PM C	CtIrTEST	49
	÷		Data 35.txt	Endpoint_B	хр	C:\Program Files (x86)	3/8/2013 2:57:38	PM C	tirTEST	50
	+	Г	Data 36.txt	Endpoint_8	хр	C:\Program Files (x86)	3/8/2013 3:08:09	PM C	tirTEST	51
				1		1	4			•

### **Creating a dedicated Template for signing samples**

Although the 21CFR-P11 Signature View may be added to any Session, it is a good idea to create a dedicated Template for the purpose of signing samples, such as in the example above. The Template is called "Sign Samples" and contains a single View. You can make this Template yourself.

To add the 21CFR-P11 Signature View to a Session, drop down the Special Views toolbar button and select it from the list.

a 🗸	
(New) 21CFR-P11 Signature View	
(New) Note View	145

To create a dedicated template for signing samples, delete all the other Views in the Session, and save the Template as "Sign Samples". It may then be used in the future for signing samples saved to the database.

### **Signing Samples**

To sign samples, create a new Session that contains the 21CFR-P11 Signature View and browse for the samples you wish to sign. Once the Session is displayed, **select one or more samples from the list and click Add Signature**. The following dialog box is presented.

Digital Signature		×
<b>R</b>	21-CFR User Verification	E
Domain	David-THINK	
Username	David	
Full Name	David Galligan	
Password	*****	
Notes	Samples run under Spec #554	î
Reason	Approved	
	Cancel	ОК

The logged-in username and full name are displayed. Enter the Windows account password and Domain to verify who you are and enter any notes for clarification. Select a Reason from the drop down list - *Approved*, *Reviewed* and *Verified*. Click *OK* to save. If multiple samples are selected, the same signature is applied to all selected samples.

Typically the *Author* signs at the point of data storage. However, if no other signatures have been added to the sample yet, then *Author* is allowed and will appear as a selectable item in the Reason drop-down list. There can be only one *Author* signature. However, there can be multiple signatures from different users for *Approved*, *Reviewed* and *Verified*.

Selecting a sample row shows the signatures that have been entered for that sample.

The column labelled "Signed" indicates if a sample has been signed or not (any signature added).

### Adding Signature to Printed Reports

The full name of the logged-in user may be added to LabSpeed reports.

In the Report Designer, add a Text control where you would like the printed name. A good place is the page footer or page header.

Select the Text control and change the following properties -- DataField - "UserFullName", Tag - "Custom" as shown below:

🖂 😔 Detail			
	TextBox		-
	<u>₿</u> 2↓ 🖻		
	ClassName	Normal	•
	CountNullValues	False	
	DataField	UserFullName	
🖂 PageFooter	HyperLink		
Printed by n	Tag	Custom	
	Text		-

#### LabSpeed Report Designer

When printed on the report, the user's full name will be printed at that location. For example, the page footer would look like this:

Printed by: David Galligan

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## **File Monitor Service**

### **Service Overview**

The File Monitor Service may participate in the Security Permissions assigned in LabSpeed for each user. These permissions are

	Service	Stop File Monitor Service	
V	Service	Edit File Monitor Service Settings	
	Service	Edit File Monitor Service Admin Options	

Depending on the permission settings for each User, a user may or may not have the right to stop the service, edit Settings and edit the Service Options. Typically only an Administrator will be able to edit the Options.

Each time access to a permission item is requested (e.g. to Stop the Service), the credentials of the user are requested (username and password). Once logged in, the user's permission is checked and he must have permission to gain access. Once access is achieved, the user is automatically logged out.

To view the File Monitor Service window, double-click on the task bar tray icon :  $^{66}$ 

If the Feature Database Manager is installed and active, the File Monitor Service will show a new <u>Service Options</u> button that is used to turn on/off permission checking and also to enable <u>Authoring Samples</u>. The Service must be stopped in order to enable the *Options* button.

Settings	Options	Hide
Status	Stopped	Start / Continue
		Pause
		Stop
Time of Last Write: Number of Records Wi	ritten: 0	
Time Service Started: Total Records Written:	0	

### **Service Options**

Click on the *Options* button in the File Monitor Service window. The following dialog will appear:



The first two options essentially enable and disable service participation in the Permissions as defined for each user in LabSpeed. When enabled, the user is required

to login and his/her permission checked before gaining access to the permission item. If not enabled, permissions are ignored and the Service can run without security as it would normally.

The third item, *Enable 21-CFR Autnor signing after saving data to database*, allows the operator to <u>digitally sign each sample</u> immediately after it has been securely saved to the database.

### **Authoring Samples**

The File Monitor Service can participate in 21-CFR Part 11 signing of samples (*Author*) as they are saved to the database. If enabled, each time data is automatically imported and transferred to the database, the user will be presented the following dialog:

Digital Signature		×
	21-CFR Part 11 Author Verification	G
Domain	David-THINK	
Username	David	
Full Name	David Galligan	
Password	*****	
Notes	Samples run under Spec #554	
Reason	Author	
	Cancel	ок

Enter your user name and password and any special notes and click OK. You are given 3 tries before failing to sign.

An Author's signature is not required. If the user Cancels, or fails to sign, the data be saved without an Author's signature. Later, in LabSpeed, the user may batch sign samples as the *Author*.

Note: Batch signing samples as *Author* after the fact is allowed only if it is the first signature to be added for each sample.

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