DatPass Administration and MicroLab Software

Validation Manual

For compliance with the
United States Food and Drug Administration
Title 21 Code of Federal Regulations Part 11
and with GAMP 4

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Chapter 1: Introduction

This manual will guide you through the process of validating the DatPass and MicroLab software package to GAMP 4 and FDA Title 21 CFR Part 11 guidelines. This manual will provide users with a test plan for their own performance and operational qualification of DatPass and MicroLab.
The manual comprises two main sections. The first section describes the relevant sections of the FDA Title 21 CFR Part 11 and the implementation of these sections in the fourtec software package. The second section provides the necessary test sheets for DatPass and MicroLab.
It is important to understand that the implementation of these guidelines is not the sole responsibility of fourtec. The software user must undertake a large portion of the responsibility through the appropriate validation tests.

The software package consists of two programs:

- DatPass – CFR Administration application
- MicroLab– Data acquisition and analysis application, supporting fourtec's MicroLog, MicroLogPRO and MicroLite data loggers.

To validate the software package, start by testing DatPass, followed by MicroLab. Some of these tests assume that the user is familiar with the Windows interface in addition to the DatPass and MicroLab software.

Chapter 2: What is Title 21 CFR Part 11?

The Food and Drug Administration (FDA) issued the regulations *Title 21 Code of Federal Regulations Part 11.* These regulations provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The regulations apply to all FDA program areas, and are intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to promote and protect public health. Part 11 applies to any record governed by an existing FDA predicate rule that is created, modified, maintained, archived, retrieved, or transmitted using computers and/or saved on durable storage media.

Title 21 CFR Part 11 Definitions

Electronic Record

Any combination of text, graphics, data, audio, pictorial or other information representation in digital form, that is created, modified, maintained, archived, retrieved or distributed by a computer system.

Electronic Signature

A computer data compilation of any symbol or series of symbols, executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Digital Signature

An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

Closed System

An environment in which system access is controlled by persons who are responsible for the content of electronic records that is on the system.

Open System

An environment in which system access is not controlled by persons who are responsible for the content of electronic records that is on the system.

Standard Operating Procedures (SOPs)

Guidelines and rules defined by the organization implementing Title 21 CFR Part 11 compliance to instruct users what they are and are not permitted to do and how they are to perform the relevant tasks.

Fourtec Software

The dual program software package achieves compliance with FDA Title 21 CFR Part 11 with: *MicroLab* and *DatPass*. The DatPass software is the administration software, which includes features that define the users that can log into the MicroLab software, their passwords and the digital signatures the users are permitted to sign data within electronic records (files). The MicroLab software is used to access the electronic records, display the logger data, analyze the data and allow the user to add the appropriate digital signatures to the electronic records, in addition to other features.

Chapter 3: Compliance with Title 21 CFR Part 11

Title 21 CFR Part 11 Requirements		Comments on Compliance or Requirements	
§11.10 Controls for Closed Systems			
(a)	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	Yes	MicroLab will not open invalid or altered data.
(b)	The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.	Yes	To ensure data integrity, MicroLab stores data with specific formats (mlb and mpj). Data can be exported to Excel™ and stored in common formats, such as an Excel workbook or for example comma delimited or tab delimited. Only through the (mlb) and (mpj) formats can data be read back into MicroLab and only these formats support electronic signatures.
(c)	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	N/A	The customer chooses which data directory to save files to. Otherwise, the default directory *C:\Program Files\Fourier Systems\MicroLab* for *DatPass\MicroLab Data* is used. System owners must establish their own SOPs to protect and restore data files.
(d)	Limiting system access to authorized individuals.	Yes	For limited access, the customer must purchase a valid software license and dongle device, preventing access to unauthorized users.
(e)	Use of secure, computer-generated, time- stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	Yes	Every action that generates or alters an electronic record (mlb or mpj), automatically generates an entry into an encrypted log file, which can be used in audit trail. The entries are chronologically organized and cannot be edited or deleted. The entries can only be viewed using the DatPass software. It is the system owner's responsibility to create SOPs to protect and restore audit trail files.
(f)	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate	Yes	A smart and user friendly interface ensures all MicroLab operations follow a specified order. This ensures all stages are followed.
(g)	Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	Yes	When using MicroLab, users logon with a valid username and password. All actions are recorded in an encrypted audit trial log file.

Title 21 CFR Part 11 Requirements		Comments on Compliance or Requirements	
(h)	Use of device (e.g. terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	Yes	MicroLab checks the status of the logger at each communication – errors are automatically reported.
(i)	Determination that persons who develop, maintain, or use electronic record/electronic signature systems has the education, training, and experience to perform their assigned tasks.	N/A	System owners must provide their authorized users with relevant training.
(j)	The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	N/A	System owners must develop written policy in which reliability and responsibility of each user is documented.
(k)	Use of appropriate controls over systems documentation including:		
(k)(1)	Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.	N/A	The MicroLab and DatPass Package for Title 21 CFR Part 11 compliance are supplied with detailed user guides and help files, which can be used to create SOP. Distribution, access and implementation of this documentation are the responsibility of the system owner.
(k)(2)	Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	N/A	This is the responsibility of the system owner.
§11.30 Controls for Open Systems			
	Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in §11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.	N/A	MicroLab has been implemented as a closed system.

Title 21 CFR Part 11 Requirements		Comments on Compliance or Requirements	
§11.50 Signature Manifestations			
(a)	Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:		
(a)(1)	The printed name of the signer;	Yes	Stored and printed data contains: User login name, time/date stamp, and user signature meaning(s).
(a)(2)	The date and time when the signature was executed;	Yes	
(a)(3)	The meaning (such as review, approval, responsibility, or authorship) associated with the signature	Yes	
(b)	The items identified in paragraphs (a)(1),(a)(2), and (a)(3)of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	Yes	Electronic signatures in MicroLab are subject to the same requirements as electronic records. Electronic signatures can be viewed electronically and can be included on a printout.
§11.70 Signature/Record Linking			
	Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred so as to falsify an electronic record by ordinary means.	Yes	In MicroLab, raw data and electronic signatures are permanently linked in a single file, and as such cannot be edited, deleted or separated.
§11.100 General Requirements			
(a)	Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	Yes	DatPass software contains an authorized user list containing login name, password, and meanings list, making every user unique to the system.
(b)	Before an organization establishes, assigns, certifies or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	N/A	This is the responsibility of the system owner.
(c)	Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.	N/A	This is the responsibility of the system owner.

Title 21 CFR Part 11 Requirements		Comments on Compliance or Requirements	
(c)(1)	The certification shall be submitted in paper form, and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100),5600 Fishers Lane, Rockville, MD 20857.	N/A	This is the responsibility of the system owner.
(c)(2)	Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.	N/A	This is the responsibility of the system owner.
§11.200 Electronic Signature Components and Controls			
(a)	Electronic signatures that are not based upon biometrics shall:		
(a)(1)	Employ at least two distinct identification components such as an identification code and password.	Yes	DatPass Software for Title 21 CFR Part 11 compliance uses a unique dual component combination: Login username and password. Every login and new digital signature with MicroLab requires a valid username and password. MicroLab enforces the user to re-logon after a time period, which is defined by the administrator via the DatPass software.
(a)(1)(i)	When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual	Yes	
(a)(1)(ii)	When an individual executes one or more signings not performed during a single continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.	Yes	
(a)(2)	Be used only by their genuine owners;	N/A	Information confidentiality is the responsibility of the system owner and users.
(a)(3)	Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	N/A	Information confidentiality is the responsibility of the system owner and users.

Title 21 CFR Part 11 Requirements		Comments on Compliance or Requirements	
(b)	Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	N/A	Biometrics are not the basis of electronic signatures generated by DatPass software for Title 21 CFR Part 11 compliance.
§11.300 Controls for Identification Codes/Passwords			
	Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:		
(a)	Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	Yes	Since every user is unique in the MicroLab and DatPass systems, duplicate combinations of username and password are impossible.
(b)	Ensuring that identification code and password issuances are periodically checked, recalled, or revised, (e.g. to cover such events as password aging).	Yes	Adequate aging of passwords is the responsibility of the system owner. MicroLab allows authenticated users to change their own logon password.
(c)	Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	N/A	Unauthorized access is vetoed by the DatPass software since an administrator can disable or remove any user from the system.
(d)	Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	Yes	All unsuccessful logons are recorded in the audit trail log file.
(e)	Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information, to ensure that they function properly and have not been altered in an unauthorized manner.	N/A	This is the responsibility of the system owner.

References

For further information on FDA Title 21 CFR Part 11, please visit the FDA website:
www.fda.gov
For FDA guidance documents:
www.fda.gov/ora/compliance_ref/part11/

Chapter 4: DatPass Validation Tests

1 - Initial Login

Following DatPass installation, you will be required to start the 30-day free trial period or to activate the software using the unique product serial number supplied with the software CD. Until either of these actions is performed, the user won't be able to login to DatPass.

Note: Following installation, the first user to login to the DatPass software is automatically assigned the user name *Admin*. He is classified as an Administrator.

Test #	Test Description	Expected Result	Result
1.1	Double click the **DatPass** shortcut on the Desktop.	Verify that the *User Login* dialog box opens.	
1.2	Click **New User** in the login window**.**	a. Verify that the *New User Login* window opens. b. Verify that the *New User* drop-down menu displays the *Admin* user name**.**	
1.3	a. Populate the *New User ID*, *Confirm User ID*, *New Password* and *Confirm Password* fields, and click **OK**. b. Exit the DatPass software. c. Launch the DatPass software.	a. Once DatPass is launched, verify that the *User Login* window opens. b. Verify that the newly created User ID and User Password are correct (click **OK** and verify successful login to DatPass).	

2 - File Menu

Test #	Test Description	Expected Result	Result
2.1	On the **File** menu**,** click **Open**. Navigate to: *C:\Users\Public\fourtec\DatPass.* **Note:** You will only find database files saved in this directory if previous database data, such as the Audit Trail log, has been saved.	a. Verify that the *Open* dialog box opens. b. Select a file to open, and click **Open.** c. Verify that the database file (file extension .mdb) opens, and the table data is displayed in the main DatPass window.	
2.2	On the **File** menu, click **New**.	Verify that the DatPass main window is clear of all previous Audit Trail data.	
2.3	On the **File** menu, click **Print**. **Note:** For this action to succeed, the main DatPass window must be populated with Audit Trail log data.	Verify that the *Print Dialog* dialog box opens.	

Test #	Test Description	Expected Result	Result
2.4	On the **File** menu, click **Print Setup**.	Verify that the *Print Setup* dialog box opens.	
2.5	On the **File** menu, click **Log off**.	Verify that the *User Login* dialog box opens.	

3 - Administration

Test #	Test Description	Expected Result	Result
3.1	On the **Administration** menu, click **User Administration.**	a. Verify that the *User Administration* dialog box opens. b. Verify that *Admin* appears under the *User Name* tab and *Administrator* appears under the *Group* tab.	
3.1.1	a. In the *User Administration* dialog box, click **Add User**. b. Enter a new user name in the *User Name* field. c. Select a Group from the Group drop-down menu: Administrator, Approver, or User. Under the *Login Settings* heading: d. Enter a number in the *Password min length* field (for example, 4). e. Enter a number in the *User ID min length* field (for example, 4). f. Enter number of days in the *Password expiration time (days)* field (for example, 1). g. Use the drop-down menu in the *Inactivity Timeout* field to select the duration (for example, 00:05:00). h. Click **OK.**	Verify that a new user has been added to the *User Administration* dialog box, listing the correct User Name and Group.	
3.1.2	a. Launch the DatPass software and add click **New User.** b. Using the new user account created in test 3.1.1, fill in the *New User ID*, *Confirm New User ID*, *New Password* and *Confirm Password* fields. c. Click **OK**.	Verify that the DatPass software opens.	

Test #	Test Description	Expected Result	Result
3.1.3	Launch the DatPass software. In the *User Login* dialog box: a. Enter an incorrect user name and a correct password. b. Enter a correct user name and an incorrect password. c. Enter an incorrect user name and password.	Verify that in all three login tests, the DatPass software does not open.	
3.2	In the *User Administration* dialog box, select the newly added user (see test 3.1.1) and click **Properties.**	a. Verify that the **User Properties** dialog box opens. b. Verify that the properties entered when adding the user (in test 3.1.1) are correct.	
3.2.1	a. In the *User Properties* dialog box, change the user group using the drop-down menu in the *Group* field. For example, from *User* to *Approver*). b. Click **OK**.	Verify that the user group was successfully changed by reopening the User Properties dialog box and checking the Group field.	
3.2.2	a. In the *User Properties* dialog box, change the *Login Settings*. b. Click **OK**.	Verify that the *Login Settings* were successfully changed by reopening the User Properties dialog box and checking the relevant Login Settings.	
3.3	In the *User Administration* dialog box, select a user and click **Deactivate.**	Verify that the user icon is now marked with a white cross in a red background, as follows: 	
3.3.1	Open the DatPass software and attempt to login with the user name and password of the newly deactivated user.	Verify that a dialog box opens with the message: *Your user account was deactivated. Please refer to your system administrator.*	
3.3.2	a. In the *User Administration* dialog box, select the previously deactivated user and click **Activate**. b. Exit DatPass, then reopen DatPass and login with the user name and password of the newly activated user.	Verify that you are able to successfully login to DatPass.	

Test #	Test Description	Expected Result	Result
3.3.3	a. In the User Administration dialog box, select a user and click **Renew Password**. b. Exit DatPass, and then reopen DatPass and attempt to login with that user.	a. Verify that a new DatPass dialog box opens with the message: *Your password was reset. Please enter a new password.* b. After clicking **OK,** verify that a new *Change Password* dialog box opens.	
3.3.4	a. In the *Change Password* dialog box, enter a new password and then confirm this password. b. Click **OK**.	Verify that the DatPass software opens.	
3.3.5	Launch the DatPass software and login using the user name and new password created in step 3.3.4.	Verify that the DatPass software opens.	
3.4	On the **Administration** menu, click **Group Administration.**	a. Verify that the *Group Administration* dialog box opens. b. Verify that the group names *User*, *Approver* and *Administrator* are displayed.	
3.4.1	In the *Group Administrator* dialog box, click **Add Group.**	Verify that the *Group Properties* dialog box opens.	
3.4.2	a. In the *Group Properties* dialog box, enter a new name in the *Group Name* field. b. Click the *New* check box. c. Click **OK**.	a. Verify that the *Group Administration* dialog box opens. b. Verify that the newly created group is displayed in the *Group Name* list.	
3.4.3	In the *Group Administrator* dialog box, select the newly created group and click **Properties.**	Verify that there is only one check box selected (in this case, *New*).	
3.4.4	In the *Group Administrator* dialog box, select one of the listed groups and click **Remove Group.** **Note:** You will not be able to remove a group if there are still users who are members of this group.	a. Verify that a dialog box opens with the message: *Are you sure you want to remove <Group Name> group?* b. Click **Yes**.	
3.4.5	On the **Administration** menu, click **Group Administration.**	Verify that the group you have removed is no longer displayed in the *Group Name* list.	

4 - Help

Test #	Test Description	Expected Result	Result
4.1	On the **Help** menu, click **DatPass User Guide.**	Verify that the DatPass v4.0 User Guide is opened (file name: User	

		Guide.pdf)	
4.2	On the **Help** menu, click **Register**.	a. Verify that the Validata – Product Validataion window is opened. b. DatPass will either be in the Trial mode, or will already be activated.	
4.3	On the **Help** menu, click **About DatPass.**	c. Verify that DatPass version 4.0.0.0 is displayed. d. Verify the link http://www.fourtec.com works.	

5 - Toolbar Icons

Test #	Icon	Test and Expected Result	Result
5.1	Open 	Refer to test 2.1.	
5.2	Print 	Refer to test 2.3.	
5.3	User Administration 	Refer to tests 3.1 to 3.3.	
5.4	Group Administration 	Refer to test 3.4.	
5.5	Refresh 	*a.* Perform at least one action in the MicroLab software and click **Refresh**. b. Verify that the Audit Trail data has been refreshed (you will see new actions added to the table).	

Chapter 5: MicroLab Validation Tests

1 - Login

Test #	Test Description	Expected Result	Result
1.1	a. Launch the MicroLab software. The *User Login* dialog box opens. b. In the *User ID* field, enter the User ID created in test 1.3 of the DatPass Validation Test. c. In the *User Password* field, enter an *incorrect* password.	Verify that the MicroLab software does not open and an *Incorrect Password* message window opens.	
1.2	a. In the *User Login* dialog box, in the *User ID* field, enter an *incorrect* User ID. b. In the *User Password* field, enter the User Password created in test 1.3 of the DatPass Validation Test.	Verify that the MicroLab software does not open and an *Incorrect User ID* message window opens.	
1.3	In the *User Login* dialog box, enter an incorrect User ID and User Password.	Verify that the MicroLab software does not open and an *Incorrect User ID* message window opens.	
1.4	In the *User Login* dialog box, login using the User ID and User Password created in test 1.3 of the DatPass Validation Test.	Verify that the MicroLab software is launched.	

2 - File Menu

Test #	Test Description	Expected Result	Result
2.1	On the **File** menu**,** click **New.**	Verify that the MicroLab main window is clear i.e. there is no data in the graph and table in the main window.	
2.2	On the **File** menu**,** click **Open.**	Verify that the *Open* dialog box opens.	
2.2.1	In the *Open* dialog box, select a file and click **Open.**	Verify that the selected file opens, and that the appropriate data is displayed in the graph and table in the main window.	
2.3	On the **File** menu**,** click **Save As.**	Verify that the *Save As* dialog box opens.	

Test #	Test Description	Expected Result	Result
2.3.1	a. In the *Save As* dialog box, in the *File name* field, enter the name of the file to be saved. b. Click **Save**.	a. Verify that the file was actually saved. Navigate to: *C:\Programs Files\Fourier Systems\MicroLab for DatPass\MicroLab Data*. b. Verify that the file was saved in the *MicroLab* folder.	
2.4	On the **File** menu, click **Display Properties**.	Verify that the *Display properties* dialog box opens.	
2.4.1	Under the *Decimal place settings* heading in the *Display Properties* dialog box: a. Change the *Temperature data* field to *3*. b. Change the *Humidity data* field to *2*. c. Change the *External data* field to *1*. d. Click **OK.**	Verify that in the data table in the main MicroLab window, the decimal places for the temperature and humidity data (and any external sensors) have been updated accordingly.	
2.4.2	In the *Display properties* dialog box, under the *Date format settings* heading are four options for the date format. Click on any one of the formats not already selected.	a. Verify that for the graph in the main MicroLab window, the Time (*x*) axis has been updated accordingly. b. Verify that for the data table in the main MicroLab window, the Time (Date) column has been updated accordingly.	
2.5.	On the **File** menu, click **Print**.	Verify that the *Print options* dialog box opens.	
2.5.1	In the *Print options* dialog box, click the *Graph* radio button.	Verify that the *Report data selection* option is disabled.	
2.5.2	In the *Print* options dialog box: a. Click the *Graph* radio button. b. Click **Print.**	Verify that the *Print* dialog box opens.	
2.5.2.1	In the *Print* dialog box, confirm that the correct printer is selected in the *Name* drop-down menu and click **OK**.	Verify that the graph was printed at the selected printer.	
2.5.3	In the *Print options* dialog box: a. Click the *Table* radio button. b. Under the *Report data selection* heading, ensure the *Print all data* check box is selected. c. Click **Print**.	Verify that the *Print* dialog box opens.	

Test #	Test Description	Expected Result	Result
2.5.3.1	In the *Print* dialog box, confirm that the correct printer is selected in the *Name* drop-down menu and click **OK**.	Verify that the graph was printed with all of its data (as defined in test 2.5.3), at the selected printer.	
2.5.4	In the *Print options* dialog box: a. Click the *Table* radio button. b. Under the *Report data selection* heading, ensure the *Print all data* check box is **not** selected, thereby enabling the *From* and *To* fields. c. Using the *From* and *To* fields, define the date and time range to print. d. Click **Print**.	Verify that the *Print* dialog box opens.	
2.5.4.1	In the *Print* dialog box, confirm that the correct printer is selected in the *Name* drop-down menu and click **OK**.	Verify that the graph was printed with the specific date and time range (as defined in test 2.5.4), at the selected printer.	
2.6	On the **File** menu, click **Print Setup**.	Verify that the *Print Setup* dialog box opens.	
2.7	On the **File** menu, click **Log Off.**	Verify that the *User Login* dialog box opens.	

3 - View Menu

Test #	Test Description	Expected Result	Result
3.1	On the **View** menu, click **Display Data map** to unselect it (removing the tick by the menu entry).	Verify that the Data Map pane has been removed from the left of the main MicroLab window.	
3.2	On the **View** menu, click **Display Graph** to unselect it (removing the tick by the menu entry).	Verify that the graph has been removed from the center of the main MicroLab window.	
3.3	On the **View** menu, click **Display Table** to unselect it (removing the tick by the menu entry).	Verify that the table has been removed from the right of the main MicroLab window.	

4 - Graph Menu

Note: In order to perform the tests in this section, a graph must be displayed in the main MicroLab window. Refer to test 2.2 regarding opening a file.

Test #	Test Description	Expected Result	Result
4.1	a. On the **Graph** menu, click **Graph Properties**. b. Ensure that *Time* is selected in the *Select axis* drop down menu. c. Ensure the *Auto scale* check box is not selected, thereby enabling the *From* and *To* fields. d. Using the *From* and *To* fields, define a new date and time range. e. Click **OK**.	Verify that the time scale of the graph in the main MicroLab window has been updated accordingly.	
4.1.1	a. In the *Graph properties* dialog box, click **Set default zoom**. b. In the *Default zoom setting* dialog box, enter a time range in the *Start* and *End* fields. c. Click **Set.** d. Click the *Use default zoom* check box. e. Click **OK.**	Verify that the time scale of the graph in the main MicroLab window has been updated accordingly.	
4.1.2	a. In the *Graph properties* dialog box, select *Temperature* in the *Select axis* drop-down menu. b. The *Min* and *Max* temperature fields are now active. Enter *–26* in the *Min* field and *22* in the *Max* field. c. Click **OK**.	Verify that the temperature scale of the graph in the main MicroLab window has been updated accordingly.	
4.1.3	a. In the *Graph properties* dialog box, click the **Lines** tab. b. Select *Time* in the *Select plot* drop-down menu. c. Change the *X Axis* color to red, by using the *Color* drop-down menu.	Verify that the *Time* axis of the graph in the main MicroLab window is now red.	

Test #	Test Description	Expected Result	Result
4.1.4	a. In the *Graph properties* dialog box, click the **Lines** tab. b. Select *Temperature* in the *Select plot* drop-down menu. c. Under the *Line* heading, ensure the *Visible* check box is selected. d. Change the Temperature axis color to green, using the *Color* drop-down menu. e. Using the *Style* drop-down menu, select the solid line option. f. Using the *Weight* drop-down menu, select the thinnest line option.	In the graph in the main MicroLab window, verify that the *Temperature* axis is green and the line plotting the temperature data is green, solid and thin.	
4.1.5	*For MicroLog EC650 and MicroLogPRO EC750 only:* a. In the *Graph properties* dialog box, click the **Lines** tab. b. Select *Humidity* in the *Select plot* drop-down menu. c. Under the *Line* heading, ensure the *Visible* check box is selected. d. Change the Humidity axis color to yellow, using the *Color* drop-down menu. e. Using the *Style* drop-down menu, select the solid line option. f. Using the *Weight* drop-down menu, select the thinnest line option.	In the graph in the main MicroLab window, verify that the *Humidity* axis is yellow and the line plotting the humidity data is yellow, solid and thin.	
4.1.6	a. In the *Graph properties* dialog box, click the **Lines** tab. b. Click **Restore defaults.**	Verify that all axis and line defaults have been restored in the graph in the main MicroLab window.	
4.2	On the **Graph** menu, click **Export Graph to Excel**.	Verify that the displayed graph is exported to Excel.	

Test #	Test Description	Expected Result	Result
4.3	a. On the **Graph** menu, click **Zoom**. b. Click down and hold the left mouse button and drag the *Zoom* cursor over the area of the graph to be zoomed. c. Release the left mouse button to set the zoom area.	Verify that the selected area of the graph is zoomed in.	
4.4	On the **Graph** menu, click **Autoscale**.	Verify that the graph in the main MicroLab window is restored and displayed in full.	
4.5	a. On the **Graph** menu, click **Crop**. b. Click down and hold the left mouse button and drag the *Crop* cursor over the area of the graph to be cropped. c. Release the left mouse button to crop the selected area.	Verify that the selected area of the graph has been cropped – only the selected area should be visible.	
4.6	a. On the **Graph** menu, click **Copy Graph**. b. Paste the graph into another application such as *Microsoft Office Word*.	Verify that the graph has been successfully copied.	
4.7	On the **Graph** menu, click **Dew Point** and select *Internal Temperature*.	Verify that the dew point is shown on the graph in the main MicroLab window.	

5 - Logger Menu

Note: Ensure that the data logger (MicroLog, MicroLogPRO or MicroLite) is connected to the PC and is recognized by the MicroLab software.

Test #	Test Description	Expected Result	Result
5.1	a. On the **Logger** menu, click **Setup Logger**. b. In the *MicroLog/MicroLite info* section of the *Setup* dialog box, enter a new name to identify the data logger in the *Comment* field. c. Click **Send Setup**.	*MicroLog/MicroLite Info Section Verification* a. Enter the *Setup* dialog box and verify that the *Comment* field is correctly updated. b. Verify that the S/N is correct for the logger that is currently connected to MicroLab. c. Verify that the logger firmware version number is displayed. d. Verify that the arrow on	

Test #	Test Description	Expected Result	Result
		the Battery Level meter is located on the far right of the green bar (for full batteries).	
5.2	a. On the **Logger** menu, click **Setup Logger**. In the *Setup* section of the *Setup* dialog box: b. Click either the º C or º F radio button next to the *Temperature unit* heading. c. In the *Interval (hh:mm:ss)* field, select the time interval for MicroLog sampling (from 10 secs to 2 hours for MicroLog or from every second to 2 hours for MicroLite). d. Click the *Timer run* check box. Using the *Timer run* date and time fields, set the time for the data logger to begin sampling. e. Click **Send Setup.**	*Setup Section Verification* a. Enter the *Setup* dialog box. b. If the connected logger comes with both *Temperature* and *Humidity* internal sensors, verify that both of the check boxes for these sensors are selected. c. If the connected logger only comes with the *Temperature* internal sensor, verify that the check box for this sensor is selected and that the *Humidity* and *External* sensor check boxes are not selected (and N/A is displayed). d. Verify that when the *Interval* is adjusted (test 5.2c), the *Recording time* also self-adjusts. e. Verify that all updates made in test 5.2 have been updated in the *Setup* dialog box. f. After exiting the *Setup* dialog box, download the logger data and verify (in the data table) that the data date and time range, as well as the data interval, correspond with what you defined in Setup.	

Test #	Test Description	Expected Result	Result
5.3	a. On the **Logger** menu, click **Setup Logger**. In the *Alarm levels* section of the *Setup* dialog box: b. Enter new *Low* and *High* values in the *Temperature* and *Humidity* fields. c. Click **Send Setup**. d. Download data from the logger into MicroLab, so that the data is displayed in a graph in the main MicroLab window. e. Click the *Show Alarm levels* icon  in the MicroLab tool bar. Select *Temperature* from the adjacent drop-down menu, and then select *Humidity* (if connected logger has a humidity sensor).	a. In the main MicroLab window, verify that the *Low* and *High* alarm levels for both *Temperature* and *Humidity* (if relevant) appear on the graph as a light blue and light red line respectively. b. Verify that these alarm levels correspond to the alarm levels previously defined in the Setup.	
5.3.1	a. On the **Logger** menu, click **Setup Logger**. In the *Alarm levels* section of the *Setup* dialog box: b. Click **Cancel alarm levels** to restore the default levels adjusted in test 4.2. c. Click **Send Setup.** d. Repeat tests 5.3d and 5.3e above.	a. In the MicroLab main window, verify that the *Low* and *High* alarm levels for both *Temperature* and *Humidity* (if relevant) appear on the graph as a light blue and light red line respectively. b. Verify that the default alarm levels have been restored as follows: ***MicroLog:*** *Temperature:* Low: -30 °C/-22 °F, High: 50 °C/122 °F *Humidity:* Low: 0, High: 100 ***MicroLogPRO:*** *Temperature:* Low: -40 °C/-40 °F, High: 80 °C/176 °F *Humidity:* Low: 0, High: 100 ***MicroLite:*** *Temperature:* Low: -40 °C/-40 °F, High: 80 °C/176 °F	
5.4	a. On the **Logger** menu, click **Setup Logger**. b. In the *Setup* dialog box, click **Send Setup**.	a. Verify that the message: *Setup will clear the MicroLog/MicroLite memory. Do you want to continue?* appears. Click **Yes**. b. Verify that the *Reason Dialog* box opens. Enter a reason for performing this action e.g.	

Test #	Test Description	Expected Result	Result
		Test. c. Verify that the *Status* window opens and that all statuses are successfully sent (noted with a green check mark). A *Completed* status should appear at the bottom of this window. d. Click **Close**. **Note:** The **Set Cradle** status will only be sent if a Cradle is connected and recognized by the MicroLab.	
5.5	On the **Logger** menu, click **Download.**	Verify that the logger data is downloaded into the MicroLab main window. **Note:** Ensure that the logger has been recording data to download.	
5.6	On the **Logger** menu, click **Run.**	a. Verify that the message: *Run will clear the MicroLog/MicroLite memory. Do you want to continue?* appears. b. Verify that the *Reason Dialog* box opens. Enter a reason for performing this action e.g. Test. c. Verify that the logger is recording data.	
5.7	On the **Logger** menu, click **Stop.**	a. Verify that the *Reason Dialog* box opens. Enter a reason for performing this action e.g. Test. b. Verify that the logger is in Stop mode and is not recording data.	
5.8	On the **Logger** menu, click **Set Celsius.**	Verify that the temperature data is shown in the logger LCD display in *Celsius.*	
5.9	On the **Logger** menu, click **Set Fahrenheit.**	Verify that the temperature data is shown in the logger LCD display in *Fahrenheit*.	
5.10	On the **Logger** menu, click **Com Setup.**	a. Verify that the *Communication Setup* dialog box opens. b. Verify that the logger you have connected to the PC is identified. The check box for the port to which the logger is connected should be selected. Verify that the message *MicroLog/MicroLite is connected* appears.	

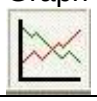
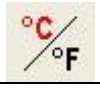
Test #	Test Description	Expected Result	Result
5.10.1	On the **Logger** menu, click **Com Setup.** In the *Communication Setup* dialog box, click **Try to connect.**	a. Verify that the PC ports are being scanned. b. Verify that a confirmation message appears indicating that the MicroLog/MicroLite is detected.	

6 - Help Menu

Test #	Test Description	Expected Result	Result
6.1.	On the **Help** menu, click **About MicroLab.**	a. Verify that the *About MicroLab* dialog box window opens. b. Verify that the MicroLab version number and copyright are displayed. c. Verify the link http://www.fouriersystems.com/ works.	
6.2.	On the **Help** menu, click **MicroLog Help.**	Verify that the *MicroLog Help* file opens.	

7 – Main Toolbar Icons

Test #	Icon	Test Description and Expected Result	Result
7.1	Open 	Click this icon and refer to test 2.2.	
7.2	Save 	a. Clicking the **Save** icon will save the current data. b. Verify that the data was saved by following test 2.2 and opening the data file which was just saved.	
7.3	Print 	Click this icon and refer to test 2.5.	
7.4	Export 	Click this icon and refer to test 4.2.	
7.5	Run 	Click this icon and refer to test 5.6.	
7.6	Stop 	Click this icon and refer to test 5.7.	
7.7	Setup 	Click this icon and refer to tests 5.1 - 5.4.	
7.8	Download	Click this icon and refer to test 5.5.	

Test #	Icon	Test Description and Expected Result	Result
			
7.9	Data Map 	Click this icon and refer to test 3.1.	
7.10	Graph 	Click this icon and refer to test 3.2.	
7.11	Table 	Click this icon and refer to test 3.3.	
7.12	Statistics 	Click this icon and verify that statistics such as Min, Max and Average values appear on the bottom of the graph.	
7.13	°C/°F 	Click this icon and verify that the units on the graph and table are toggled between Celsius and Fahrenheit.	
7.14	Alarm  Data select (for Alarm) 	Click this icon and refer to test 5.3.	

8 - Graph Toolbar Icons

Test #	Icon	Test Description	Expected Result	Result
8.1	Zoom In 	a. Click the **Zoom In** icon. b. Click down and hold the left mouse button and drag the *Zoom In* cursor over the area of the graph to be zoomed. c. Release the left mouse button to set the zoom area. **Note:** Repeat this step to continue zooming in. Right click to zoom out.	a. Verify that the selected area of the graph is zoomed in. b. Verify that the right click option zooms out.	

8.2	Pan 	a. Click the **Pan** icon. b. Place the *Pan* cursor over the graph, hold down the left mouse button and proceed to pan the graph up, down, left and right.	Verify that the graph pans up, down, left and right.	
8.3	Auto scale 	a. Zoom in on an area of the graph. b. Click the **Auto scale** icon	Verify that the graph is restored and displayed in full.	
8.4	Cursor 	a. Click the **Cursor** icon. b. Drag the graph cursor to any coordinate on the graph.	a. Verify the graph cursor is displayed. b. Verify that the chosen coordinate is displayed in the first row of the table in the MicroLab main window.	
8.5	Graph Properties 	Click this icon and refer to tests 4.1 and 4.2.	Refer to test 4.1.	