

OPERATION MANUAL

FOR THE

DataTrace® Pro SOFTWARE



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Rev. # A

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1.0 GENERAL INFORMATION

This Operation Manual is intended to be used for the operation of the DataTrace Pro® (DT Pro) software. For details on computer requirements for using DT Pro or the installation of the DT Pro software refer to the Mesa Laboratories website, https://datatrace.mesalabs.com/datatrace-pro-software/.

Mesa Laboratories' DataTrace Pro (DT Pro) Software Version 1.3.1 is the key to the DataTrace® MPRF and MPIII process monitoring solution. Using DT Pro to create reports, analyze and understand data, and comply with regulatory requirements gives you greater insight and productivity for your monitoring needs.

Setup of network connectivity in DT Pro might require involvement from the customer's IT department in the event that specialized security access is part of the customer's standard operating procedures.

It is highly recommended that the Administrator of each DT Pro installation also be part of the Administrators group in Windows with full rights to change files on the local PC hard drive.

1.1 DT Pro Editions

The installed Edition will be displayed as the DT Pro background.

1.1.1 DataTrace Pro Basic:

Includes all the tools to program, read, test, and calibrate Data Loggers, create, and customize reports, and manage data. The Basic edition is not 21 CFR Part 11 compliant and does not include wireless data reception (RF) or alarming support.

1.1.2 DataTrace Pro Sentinel:

Includes the features of the Basic edition, but also includes support for RF Data Loggers and MPRF PC Interfaces. The Sentinel edition is not 21 CFR Part 11 compliant.

1.1.3 DataTrace Pro Plus:

In addition to the features of the Standard edition, includes support for 21 CFR Part 11 regulatory compliance, wireless data reception, and alarming functions.

1.1.4 DataTrace Pro LAN Server:

In addition to all the features of the Plus edition, includes the components necessary to share its database with other DataTrace Pro installations.

Note:

For a shared LAN installation, only one LAN Server edition license is required; Plus
editions include the components necessary to connect to the LAN Server database.

1.2 Upgrading DT Pro

DT Pro can be upgraded from Basic to Standard or Plus or LAN Server editions by obtaining a new License code from Mesa Laboratories, Inc or your local DataTrace distributor. In order to obtain the new License code you must provide your unique Installation ID.

The DT Pro Installation ID can be viewed by selecting the Help menu, and then selecting the About DataTrace Pro option.

Once you have obtained the new code, activate it by selecting the File menu, clicking on the License Registration option, entering the New License Code, and clicking the Activate button.

1.3 Help File

The DT Pro Help File contain detailed information about the software functionality. The Help File can be accessed by:

Selecting the Help option, and then selecting either Contents or Tutorial.



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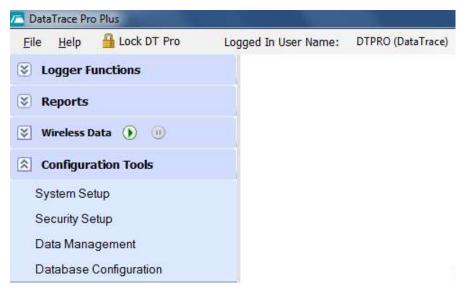
Pressing F1 while a window is open will display the Help topics for that window, if applicable.

1.4 Supported Devices

DT Pro supports MPIII Data Loggers, MPIII PC Interfaces, MPRF Data Loggers, MPRF PC Interfaces (with RF Functionality), and Network Repeaters.

DT Pro does not support legacy DataTrace products such as FRB or mA Data Loggers.

2.0 CONFIGURATION TOOLS MENU



Note:

Configuration Tools is accessible only for users with Administrator or Power User permission levels.
 If the system has been configured for Windows Authentication security mode it will be available for all access levels.

2.1 System Setup

Left click on the Configuration Tools menu, and then click on System Setup. The System Setup window will be displayed.

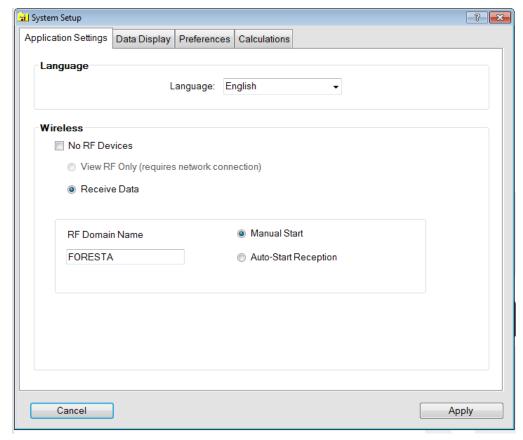
The System Setup window has four tabs that contain the different configuration options for the DT Pro software.



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2.1.1 Application Settings Tab



2.1.1.1 Language

Sets the language you wish DT Pro to use for all window displays.

2.1.1.2 Wireless Settings

Configures the Radio features you wish to use.

Note:

• Wireless data reception is available only in the DT Pro Sentinel, Plus or LAN Server editions of the software.

2.1.1.2.1 No RF Devices

Select this option if you will not be using any radio devices. Options and features associated with radio functions will be hidden.

2.1.1.2.2 View RF only

Select this option if Radio data is being received by another computer.

2.1.1.2.3 Receive Data

Select this option if there is (or will be) a MPRF PC Interface connected to your computer and you will be receiving RF data with it.



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2.1.1.2.4 RF Domain Name

The domain name is used to generate an encrypted control key which is loaded in RF capable devices (when Data Loggers are programmed, when environmental monitors or repeaters are captured, or when MPRF PC Interfaces are started).

RF control functions and data reception can only occur when the domain control key matches the system, even if RF transmissions occur on the same RF channel. If it is desired to program Data Loggers on one computer, and receive RF data on another one, both systems must be configured with the same RF domain.

RF domain name configuration applies only to systems configured to receive RF data.

2.1.1.2.5 Auto-Start Reception/Manual Start

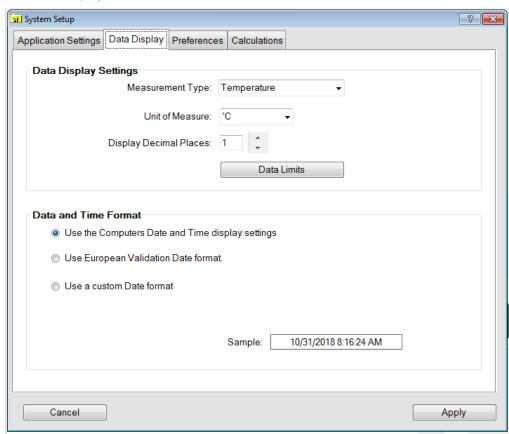
If Auto-start is selected, radio reception will begin automatically when DT Pro is opened.

An error message will be generated if there is no PC Interface connected to the computer when DT Pro is opened.

Manual Start requires the user to initiate RF data reception by

pressing in the Wireless Data menu.

2.1.2 Data Display Tab





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2.1.2.1 Data Display Settings

For each type of measurement, the unit of measure and the number of decimal points to display and print can be selected.

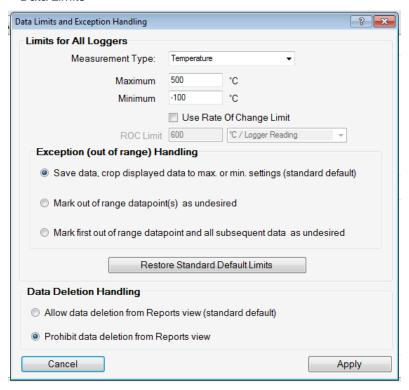
The "Time" unit selection is used in Reports for time based statistics or Pass / Fail evaluations and does not utilize decimal places.

2.1.2.2 Date and Time Format

Select how the date and time will be displayed and printed. The computer date and time format, European Date format (DD-MMM-YYYY and 24 hour clock), or a custom date format can be selected.

The sample field provides an example based on the current selection. If using a custom format, always use capital "M" for months (lower case "m" displays minutes).

2.1.2.3 Data Limits



Access to these settings is limited to system administrators only.

The settings allow minimum and maximum values to be defined for each type of data, exception handling and advanced options for data deletion.

Changes to these settings are saved only when the Apply button is clicked. All changes are recorded in the Audit Trail.

The Data Limits settings are used to mark measurements that are obviously incorrect. Incorrect measurements can occur due to Data Logger malfunction, conditions outside of the calibrated range of the Data Logger or using a Data Logger in a way it was not intended to be used (e.g. using an RH Data Logger in a condensing environment which causes the RH sensor to get wet).



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2.1.2.3.1 Measurement Type

Data limits are defined individually for each measurement type (temperature, humidity, and pressure). Use the Measurement Type drop down menu to see or set the limits for each type. The settings are:

2.1.2.3.1.1 Maximum

The highest value that will be displayed for the data type.

2.1.2.3.1.2 Minimum

The lowest value that will be displayed for the data type

2.1.2.3.1.3 Use Rate of Change Limit

If enabled, the difference between sequential data points will be evaluated and compared to the Rate of Change limit. The evaluation is dependent on the Rate of Change unit selection and can be either per logged reading), per minute, or per second.

2.1.2.3.2 Exception (out of range) Handling

These settings determine what happens when a data value is detected that is outside of the data limits maximum, minimum or rate of change settings.

2.1.2.3.2.1 Save data, crop displayed data to max. or min. settings (standard default).

Data that exceeds the defined limits will be saved; when viewed or retrieved for a report, they will be limited to either the maximum or minimums setting as appropriate.

Rate of Change Limits are not supported when this mode is used.

2.1.2.3.2.2 Mark out of range data point(s) as undesired.

Data that exceeds the limits will be saved but will be marked as undesired and will not be displayed or included in a report. It is possible to view data that has been marked as undesired by using the "Include marked data" option when retrieving data for a report.

2.1.2.3.2.3 Mark first out of range data point and all subsequent data as undesired.

Data that exceeds the limits and all subsequent data points will be marked as undesired.

If the data is received via RF, all subsequent data will also be marked as undesired until the Data Logger is programmed again.

Pressing the Restore Standard Default Limits button will set Exception (out of Range) Handling to the Save data, crop displayed data to max. or min. settings (standard default) option.



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Exceptions are calculated and handled at the time data is saved. If the data limits are changed, the change is not retroactively applied to existing data (e.g. existing data that does not pass criteria will not be marked as undesired).

2.1.2.3.3 Data Deletion Handling

These settings determine whether data can be deleted from the database using the Reports view Graph or grid.

Data deletion is always allowed using the Data Management tools, refer to Section 2.3 or additional details

2.1.2.3.3.1 Allow data deletion from Reports view (standard default).

Allows data to be deleted from the DT Pro database using the Reports menu.

2.1.2.3.3.2 Prohibit data deletion from Reports view.

Data cannot be deleted from the DT Pro database.

Notes:

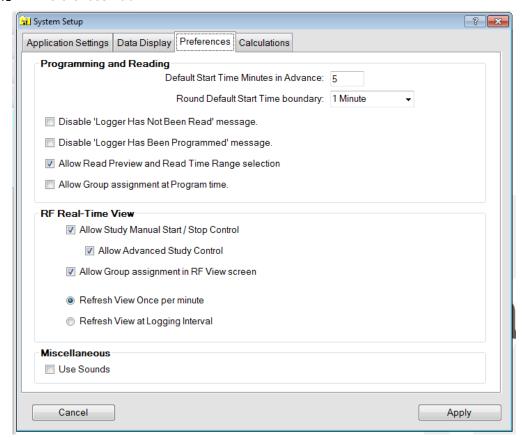
- When data is manually deleted or marked as undesired, a confirmation message with option to enter a comment or explanation for the action will appear. The action, Data Logger serial number and data range, the comment (if any) will be recorded in the audit trail.
- If data deletion is allowed, it is available only to system administrators. Marking data as undesired is available to both administrators and power users.
- For LAN installations, the Data Limit Exception and Data
 Deletion options settings are specific to each workstation;
 settings are not shared over a Network (LAN) installation.
 Automatic discarding (marking as undesired) occurs only at
 the computer where a Data Logger is read, or RF data is
 received using the settings of that workstation. Once data is
 marked, it will not be available for ready retrieval by any
 other workstation regardless of that other workstation's
 setup.



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2.1.3 Preferences Tab



2.1.3.1 Programming and Reading

2.1.3.1.1 Default Start Minutes in Advance

How far in the future the start time will be initially set to (from the time the program window opens).

2.1.3.1.2 Default Start Time Boundary

Sets whether the start time should be rounded to a specific amount of time selected from the drop down menu.

2.1.3.1.3 Disable "Logger has not been Read" message

Disables the generation of a warning message when programming a Data Logger that has not had is current data downloaded.

2.1.3.1.4 Disable "Logger has been Programmed" message

Disables the message indicating programming success.

2.1.3.1.5 Allow Read Preview and Read Time Range selection

When downloading data from a Data Logger, allows the user to specify a specific date and time range for the data.

2.1.3.1.6 Allow Group assignment at Program time

Allows the user to assign Data Loggers to different groups when programming a study.



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2.1.3.2 RF Real-Time View

2.1.3.2.1 Allow Study Manual Start / Stop control

If selected, controls will be visible in the Wireless Data window that the user can use to assign study names and manually control when a study starts or stops.

Refer to Section 4.5 for additional details.

2.1.3.2.2 Allow Advanced Study Control

When performing RF studies, the user can define a set of Processes, Locations, Alarms and Auto- allow a user to define a set of Processes, Locations, Alarms and Auto-Start/Stop conditions, customize the labels for each, and customize how a study is named based on the configuration.

It also allows the user to associate default conditions with each process and allows the operator to easily choose from the predefined conditions prior to starting a data study.

Refer to Section 4.6 for additional details.

2.1.3.2.3 Allow Group assignment in RF View Screen

MPRF Data Loggers can be assigned to different Groups using the Wireless Data Menu.

2.1.3.2.4 Refresh View Once per minute or Refresh View at Logging Interval

Data in the Wireless Data window will be refreshed per the selection.

2.1.3.3 Miscellaneous

2.1.3.3.1 Use Sounds

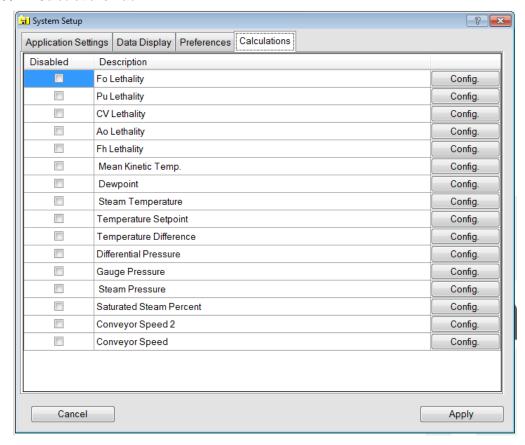
Sounds will be generated to indicate the success or failure of programming, reading, and testing operations.



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2.1.4 Calculations Tab



The "Config." button allows the user to access / set various calculation parameters.

The calculations are made using a proprietary algorithm. The basis for the algorithm is specified in the configuration menu for each calculation.

Some calculations have the configuration option to include the calculation only within the summary or to also include columnar output (e.g. show the running tally of a lethality calculation)

All calculations have the configuration option to include a comment in any reports that use the calculation. This comment is typically the parameters defined for the calculation.

Calculations (and their configurations) are performed using an external library (DTCalc.dll).

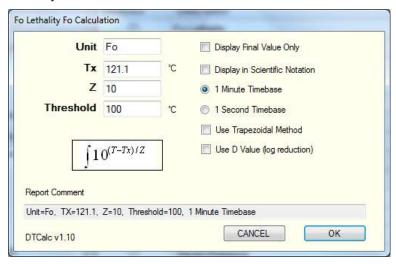


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2.1.4.1 Available Calculations

2.1.4.1.1 Lethality



Used to quantify the efficacy of a sterilization process.

Five lethality calculations can be selected, F_O, Pu, CV, A_O, or Fh. Each Lethality calculation can be configured independently.

2.1.4.1.1.1 The Tx, Z, and Threshold values can be edited if required.

Refer to the Typical Lethality Parameters topic in the DT Pro Help file for additional details on the default DT Pro Lethality Parameters.

- 2.1.4.1.1.2 The Units is the value that will be included on Reports for the Lethality calculation and can be edited if required.
- 2.1.4.1.1.3 Selecting the Display Final Value Only option allows the user to include only the final accumulated lethality value in the report.
- 2.1.4.1.1.4 Selecting the Display in Scientific Notation will display the Lethality using scientific notation, e.g. a lethality of 25.4 will be displayed as 2.54E+001.
- 2.1.4.1.1.5 The standard time base is 1 minute. The 1 second optional time base is also available but is typically used only for Ao Lethality calculations.
- 2.1.4.1.1.6 Selecting the Use Trapezoidal Method option will approximate the region under the data graph as a trapezoid and calculates the area to determine the Lethality instead of using the standard Lethality Calculation.

The Trapezoidal Method is a more conservative way of calculating Lethality and typically produces lower Lethality values.



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2.1.4.1.1.7

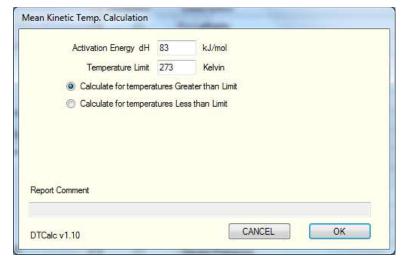
Selecting the Use D Value (log reduction) option will change the Lethality Unit to CFU and will display the Lethality results as the log reduction achieved based on the data.

The D Value can be edited after this option has been selected.

Notes:

- It is recommended that the Tx, Z, and Threshold settings be included in the calculation comment so that they appear on a printed report.
- Several F_O (or other) lethality calculations with different parameters but the same unit of measure can be defined and subsequently used in different reports.
- Language translation is not available for Lethality units. The user should edit the lethality calculation unit according to the language preference.

2.1.4.1.2 Mean Kinetic Temperature (MKT)



MKT is a special method of calculating an average temperature. The activation energy (dH) and temperature limit must be configured. The default values are 84 kJ/mol and 273 Kelvin.

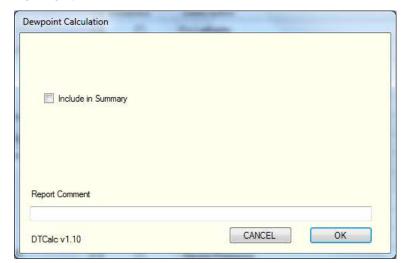
- 2.1.4.1.2.1 Selecting The Calculate for temperatures Greater than Limit option allows user to calculate MKT values for data that was above the entered Temperature Limit.
- 2.1.4.1.2.2 Selecting The Calculate for temperatures Less than Limit option allows user to calculate MKT values for data that was lower the entered Temperature Limit.



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2.1.4.1.3 Dew Point

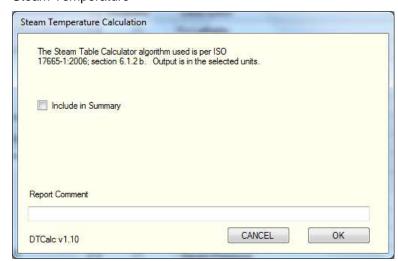


Dewpoint is a value expressed in temperature units and calculated from logged relative humidity and temperature.

The option to include the Dew Point results in the Report Summary can be selected.

Dewpoint is displayed in the selected units of measure for temperature display, refer to Section 2.1.2 for additional details.

2.1.4.1.4 Steam Temperature



Steam Temperature is a value expressed in temperature units that is calculated from logged pressure.

The option to include the Steam Temperature results in the Report Summary can be selected.

Steam Temperature is displayed in the selected units of measure for temperature display, refer to Section 2.1.2 for additional details.

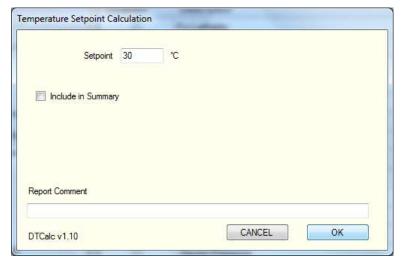
The algorithm used to calculate steam temperature is per ISO 17665-1:2006 § 6.1.2b.



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2.1.4.1.5 Temperature Setpoint

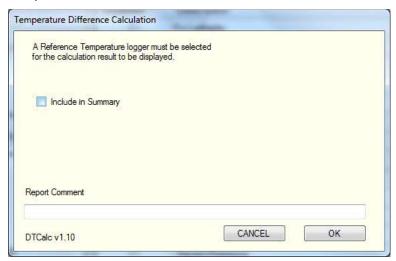


Allows the user to define a temperature set point. The result of the calculation is the difference between the measured temperatures, and the defined set point.

The option to include the Temperature Setpoint results in the Report Summary can be selected.

The Temperature Setpoint is displayed in the selected units of measure for temperature display, refer to Section 2.1.2 for additional details.

2.1.4.1.6 Temperature Difference



The option to include the Temperature Difference results in the Report Summary can be selected.

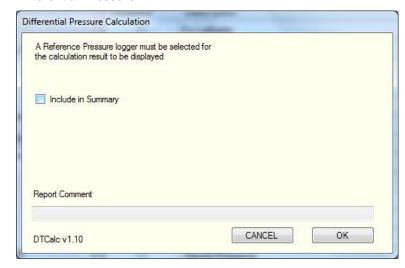
The Temperature Difference is displayed in the selected units of measure for temperature display, refer to Section 2.1.2 for additional details.



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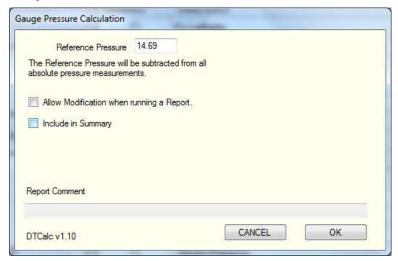
2.1.4.1.7 Differential Pressure



The option to include the Differential Pressure results in the Report Summary can be selected.

The Differential Pressure is displayed in the selected units of measure for pressure display, refer to Section 2.1.2 for additional details.

2.1.4.1.8 Gauge Pressure



Allows the user to configure a reference pressure. This pressure is subtracted from the measured pressures to produce an approximation of gauge pressure.

The option to allow modification of the reference pressure when running a report can be selected. If this option is selected a window to enter the reference pressure will open when Pressure Data Logger data is selected in the Reports Menu.

The option to include the Gauge Pressure results in the Report Summary can be selected. Refer to Section 5.2.1 for additional details.

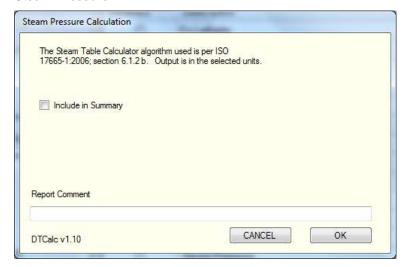


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The Gauge Pressure is displayed in the selected units of measure for pressure display, refer to Section 2.1.2 for additional details.

2.1.4.1.9 Steam Pressure

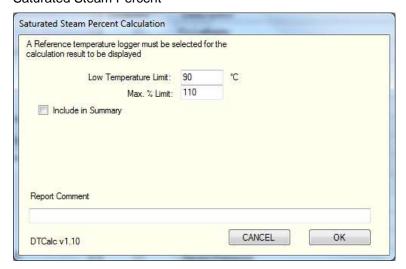


Using logged temperature, calculates the theoretical pressure for saturated steam. The algorithm used to calculate steam temperature is per ISO 17665-1:2006 § 6.1.2b.

The option to include the Steam Pressure results in the Report Summary can be selected.

The Steam Pressure is displayed in the selected units of measure for pressure display, refer to Section 2.1.2 for additional details.

2.1.4.1.10 Saturated Steam Percent



Allows the user to define a reference temperature Data Logger from which a steam pressure will be calculated. Logged pressure will be evaluated as a percentage of this theoretical pressure.



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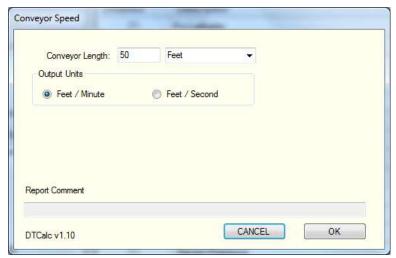
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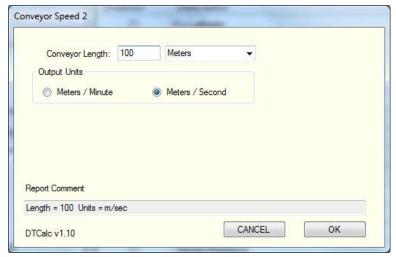
The Low Temperature limit can be defined. The calculation will not be performed if the temperature is lower that the limit.

An upper percentage limit can be defined. This is used to limit the calculation if a non-saturated steam environment was used during a study.

The option to include the Saturated Steam Percent results in the Report Summary can be selected.

2.1.4.1.11 Conveyor Speed and Conveyor Speed 2





Allows the user to define the speed of a conveyor used with the Data Loggers during a study.

The Conveyor Speed unit can be configured to report in Feet, Inches, Meters, or Centimeters and per Minute or per Second.

A phase must be defined in order for the Conveyor Speed to be calculated. The Conveyor Speed result is displayed on the Summary Tab and is the Phase duration divided by the entered unit.

Refer to Sections 5.2.2.3.7 and 5.2.3.5 for additional details.



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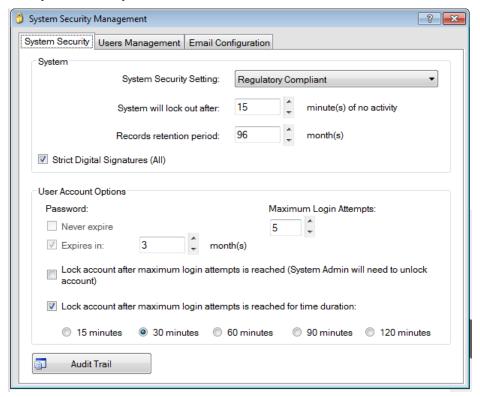
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2.2 Security Setup

Left click on the Configuration Tools menu, and then click on Security Setup. The System Security Management window will be displayed.

The System Security Management window has three tabs that contain the different security configuration options for the DT Pro software.

2.2.1 System Security Tab



2.2.1.1 System Security Setting

The level of Data Security used by DataTrace Pro is established by the Security setting. The System Security Setting can be changed at any time.

Changing the System Security Setting will reset the admin password to the default settings. Refer to Section 2.2.2.1 for additional details.

2.2.1.1.1 Windows Authentication

Relies on the Windows login system. no additional login to access the DT Pro software is required. Allows access to all functions of the program without restriction.

Encrypted, secure records are maintained, but additional checks are bypassed to increase the speed of the program. An Audit Trail is created while using this security level, refer to Section 2.2.1.6 for additional details.



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2.2.1.1.2 DT Pro Authentication

In addition to Windows Authentication security features, the DT Pro Authentication level requires the user login in order to access the DT Pro software. The user is not required to enter a password once the DT Pro software has been accessed.

An Audit Trail is created while using this security level, refer to Section 2.2.1.6 for additional details.

2.2.1.1.3 Regulatory Compliant

Complies with 21CFR Part 11 regulations.

In addition to the DT Pro Authentication security features, Encrypted, secure checks are enabled for the detection of data tampering, and users are required to enter passwords to access certain functionalities in the DT Pro software.

This security level is not available in the DT Pro Basic or DT Pro Sentinel editions.

2.2.1.2 System Lock Out

If no keyboard or mouse activity is detected for the defined time, the system will lock (will require login to re-activate). A locked system will continue to receive RF data

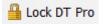
This setting does not apply to Windows Authentication mode.

A 15 minute maximum is allowed for Regulatory Compliance

A 90 minute maximum is allowed for DT Pro Authentication).

Note:

 When the DT Pro Authentication or Regulatory Compliant security modes are selected, the user can manually lock the system by clicking on



Clicking on Unlock DT Pro or attempting to close the program will open the Login screen.

2.2.1.3 Records Retention Period

When data is archived (using the Data Management option), a copy of the data, studies, alarms, etc. will be created from the oldest available data until the current date less the retention period. Once the copy has been made, the data is removed from the active database. The archived data can be subsequently accessed using the Data Management tool, refer to Section 2.3 for additional details.



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2.2.1.4 Strict Digital Signatures (All)

This option is only available when the Regulatory Compliant mode is used.

Use of this option implements a stricter interpretation: the user will be asked for a digital signature (entering a password) at the beginning of any and all activities which potentially create or modify database records of significance.

When this option is not used, DT Pro will still require digital signatures for the more significant activities such as reading Data Loggers, accessing security, defining alarms, or acknowledging alarms.

All record modifications are tracked in the Audit Trail.

2.2.1.5 User Account Options

Controls when and how Passwords expire, and what happens on failed login attempts.

| 2.2.1.5.1 | Passwor | d Expiration |
|-----------|-----------|--|
| 2.2.1. | 5.1.1 | Never Expire (only selectable in Windows Authentication or DT Pro Authentication). |
| 2.2.1. | 5.1.2 | Expires in: Password expiration can be set from 1 to 12 months. |
| 2.2.1.5.2 | Login Att | tempts |
| 2.2.1. | 5.2.1 | Maximum Login Attempts: Can be set from 1 to 5 attempts. |
| 2.2.1. | 5.2.2 | The DT Pro software can be set to Lock the User Account in 2 ways. |
| | 2.2.1.5.2 | 2.2.1 Lock the account after either the maximum |

| | login attempts are reached, this requires the System Admin to unlock the account. |
|---------------|---|
| 2.2.1.5.2.2.2 | Lock the account for a specified duration (15, 30, 60, 90 or 120 minutes). |

2.2.1.5.3 Password Requirements

The minimum requirements for password validity are:

| 2.2.1.5.3.1 | Password must be at least 8 characters long. |
|-------------|---|
| 2.2.1.5.3.2 | Password cannot be more than 32 characters long. |
| 2.2.1.5.3.3 | Password must contain a mixture of characters, numbers, or symbols. |
| 2.2.1.5.3.4 | Password reuse is not allowed for at least 4 password change events (the current password and 3 previous passwords are disallowed). |

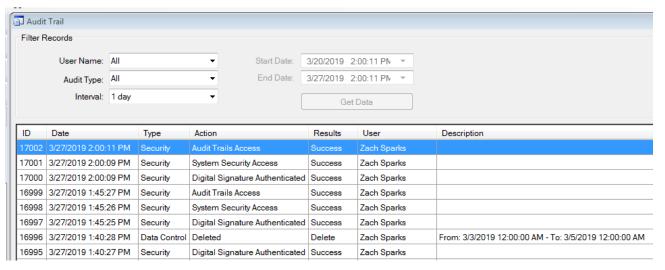


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2.2.1.6 Audit Trail

This Audit Trail function generates and maintains log of certain system events and user activities in all security modes. The audit trail can be viewed by clicking the Audit Trail button.



2.2.1.6.1 User Name

The Audit Trail can be filtered using the events created by All Users or a specific User Name.

2.2.1.6.2 Audit Type

The Audit Trail can be filtered using different event types. The Audit Trail can be filtered by All events, Data Logger events, Security events, Calibration events, Calculation events, Reports events, System events, Alarms events, Setup events, or Data Control events.

2.2.1.6.3 Interval

The Audit Trail can be filtered by events that occurred in the defined times. Users can filter the Audit Trail by events that occurred within 1 day, 1 week, 1 month, 3 months, 1 year, All, or Other.

Selecting the Other option allows the user to enter the dates and times of the Audit Trail events to display. Pressing the Get Data button will display the events.

2.2.1.6.4 Exporting the Audit Trail

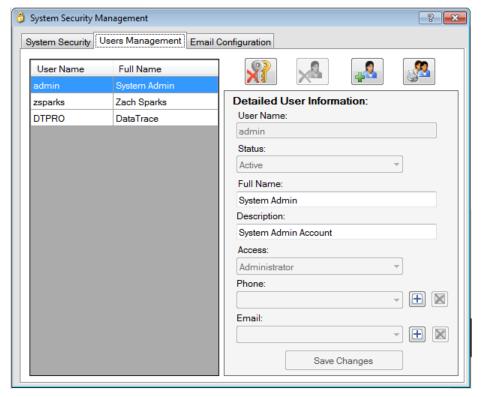
The Audit Trail can be exported as a comma delimited file (*.csv) or printed by selecting the Export option at the bottom of the Audit Trail window.



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2.2.2 User Management Tab



2.2.2.1 New Installations

On a new DT Pro installation, the system is setup with a System Admin User Account.

To log in for the very first time, use the following information:

User Name: admin Password: admin

If using DT Pro Authentication tor Regulatory Compliant System Security Settings, the Password will be required to be changed after the 1st login.

2.2.2.2 Account Setup

All User Accounts are displayed in the grid on the left side of the Tab. When a User Account is selected, the details of the account are shown in the Detailed User Information section.

The four buttons on the top of the window are used to control the User Accounts

2.2.2.2.1 Reset Password

R

The user password will be reset to match User Name.



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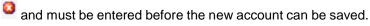
2.2.2.2.2 Delete Selected User

The user account will no longer be able to access the DT Pro software. Deleted users are still listed on the left side of the Tab but are grayed out and cannot be edited.



2.2.2.2.3 Add New User

Creates a new user account. All required entries are denoted by





2.2.2.2.4 Print Users

Creates a report of the entered information for all the user accounts.

Notes:

- When a user logs in, the user name and password are identical, and the user will be prompted to immediately enter a new password.
- Both user name and passwords are case sensitive.
- If Windows Authentication mode is used, user accounts are still required in order to create contact information (e.g. e-mail addresses) for use by the alarms system.

2.2.2.5 Detailed User Information

On the right side of the Tab, the details of the selected user account are shown. Each user account includes the following information:

| 2.2.2.2.5.1 | User Name |
|-------------|-----------|
| _ | |

The system identifier for the account.

2.2.2.2.5.2 Status

Whether the account is active or disabled. The administrator can change the account status accounts as needed.

2.2.2.2.5.3 Full Name

The full name of the user. Reports can be configured to include this information, refer to Section 5.2.5.1 for additional details.

2.2.2.5.4 Description

A reference field that can be used to include details about the account that are included on the System Security Report.



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2.2.2.2.5.5 Telephone

The telephone number of the user and is included on

the System Security Report.

2.2.2.2.5.6 E-mail

One or more e-mail addresses for the user. Used by the alarms system when a user contact has been

defined.

A text message can be sent to cell phones that support e-mail message reception or by sending the email to an address provided by the cell phone service

 $supplier \ (e.g. \ for \ Verizon \ subscribers, < cell$

number>@vtext.com).

2.2.2.2.5.7 Access

The permission level assigned to the account.

2.2.2.2.5.7.1 Administrator

Has access to all of the DT Pro software

functionality.

2.2.2.5.7.2 Power User

Has access to all of the DT Pro software functionality, except for Security Setup.

2.2.2.5.7.3 Standard User

Has access to Logger Functions, Reports, and Wireless Data menus. Does not have access to the Report Template creation or

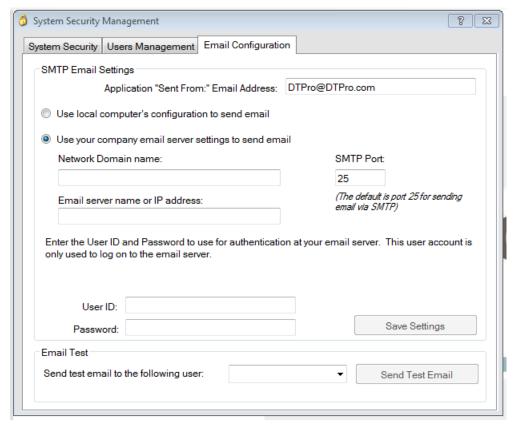
modification.



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2.2.3 Email Configuration Tab



Notes:

- In order to be able to set up the email feature in DT Pro, the PC must have SMTP Service for Windows installed. Please consult with your IT personnel for assistance.
- The functionality of all network enabled features of DT Pro, including automatic email notifications and remote database connections is dependent on your Company Network Settings.

2.2.3.1 SMTP E-mail Settings

- 2.2.3.1.1 Enter a "Sent From" address that will be used for all e-mails sent by DT Pro.
- 2.2.3.1.2 Use Local Computer's Configuration

If selected, all other options will be disabled. This option does not allow an e-mail to be sent through a fire-wall but does allow an e-mail to be with in a local network.

2.2.3.1.3 Use Company Email Server Settings

This option must be selected to send an e-mail through a fire-wall.

The required information should be available from the user's IT department.



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WARNING:

If the password has expired or changed for the User ID used to authenticate the email server, the new password must be entered, and the changes saved by pressing the Save Settings button.

A user account can be used that is restricted to e-mail use only and does not have a password expiration.

It is recommended all e-mail functions be verified using the Send Test Email button for the various users.

2.2.4 Data Security

All data and configuration information is stored in the DT Pro SQL database. The various elements of the database are password protected to limit access. This protection exists regardless of the system security setting.

When the Regulatory Compliant mode is enabled, in addition to the various requirements for storage of digital signatures, an encrypted security key is stored in data records, studies, calibration records, configuration or alarm records, and any other records deemed to be of significance for compliance. Regardless of the security setting, a security key is always generated for all audit trail records.

The security key is specific to each record type, the specific data contained within the electronic record and the digital signature as applicable. The encrypted security key is subsequently used to detect data tampering in the event the database password protection is compromised.

The security key is not included when lower security modes are used. Data gathered in lower security modes will fail security key checks if regulatory compliant mode is subsequently enabled; and this will be evident in the various data views and reports, as would any failure of the security key check.

Along with the security key, the actual data related to security configuration and user accounts (e.g. passwords) is also encrypted. Security keys and encryption details are also contained within or applied to database back-up files or archive files.

A read only database password is available for those who wish to access measurement data directly via ODBC, SQL query or third party software. The measured data is subject to tampering detection but is itself not encrypted so as to provide access. Data that is accessed by direct database query, third party software, exported, or copied from the DT Pro system into some other application will most likely no longer meet the requirements for 21 CFR Part 11 compliance. Access passwords for the security settings are not available and details about the encryption algorithms or security keys will not be disclosed.

In addition to the provided security settings, data limits, exception handling and data deletion options can be configured by System Administrators. Refer to Section 2.1.2.3 for additional details.

2.3 Data Management

Left click on the Configuration Tools menu, and then click on Data Management. The Database Utilities Wizard will be displayed.

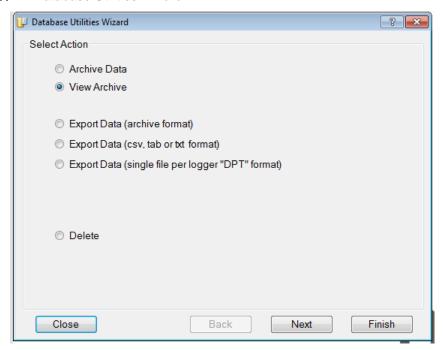
Access to Data Management is not available while RF data reception is active.



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2.3.1 Database Utilities Wizard



The Database Utilities wizard contains tools for Archiving, Exporting, or Deleting data. To access the wizard, expand Configuration Tools and click the Data Management button. Select from the following options:



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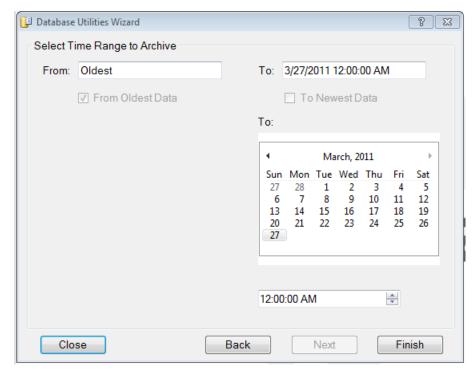
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2.3.1.1 Archiving or Exporting Data

2.3.1.1.1 Archive Data

Creates a binary and secured archive data file.

After the archive data file has been created the data is deleted from the database.



By default, all data that is older than the Active Record Retention Period is archived.

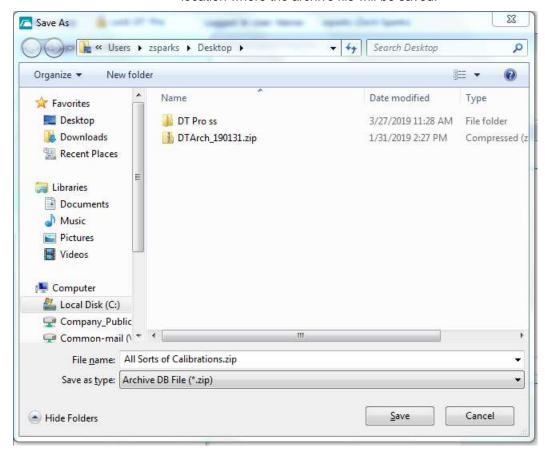
The user can select a different date and time range, as long as the range begins prior to the Active Record Retention Period setting, refer to Section 2.2 for additional details.



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2.3.1.1.1.1 Clicking on Finish will open a window to select the location where the archive file will be saved.



Notes:

- The archive file will contain a copy of the currently selected Report Template. The option to include all Report Templates in the archive file will be displayed during the Archiving proves.
- By default, the file name of an archive file begins with "DTArch" and contains date codes indicating the data range (day / month / year format). The file extension of an archive is ".ZIP".
- Archive files contain security elements and digital signatures to assure regulatory compliance when printing a report from an archive.



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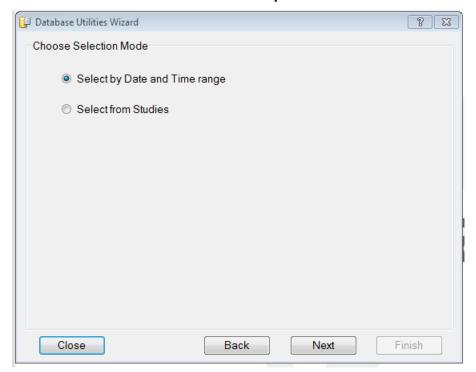
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2.3.1.1.2 Export Data

Creates a file of the data that can be imported into other applications or e-mailed.

2.3.1.1.2.1 The Export Data (Archive Format) option creates a binary and secure archive data file.

Data is not deleted from the database after the archived data has been exported.

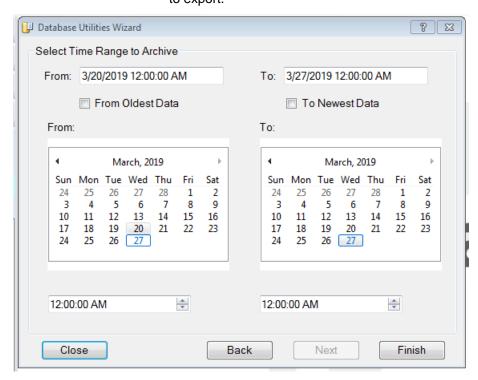




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2.3.1.1.2.1.1 The Archive Format Data can be exported by using the Select by Data and Time Range option and then selecting the range to export.





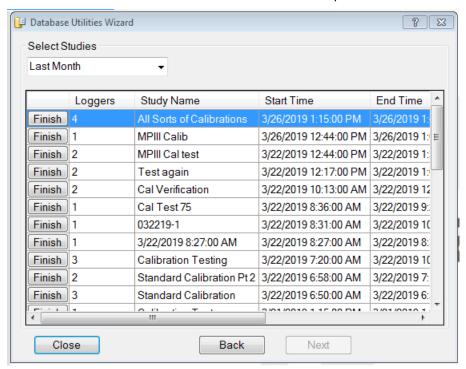
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2.3.1.1.2.1.1

The Archive Format Data can also be exported by using the Select from Studies option and the selecting the Study to export.

The range of the Studies that are displayed can be selected from the Drop Down Menu.

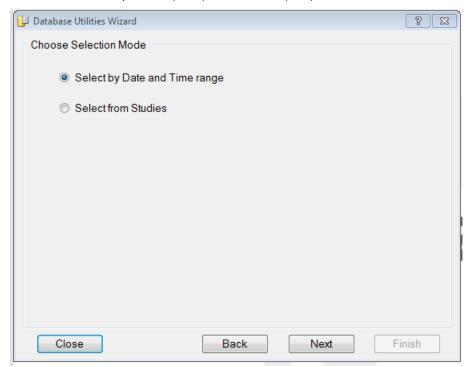




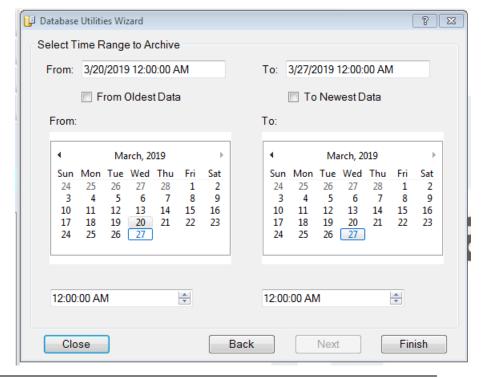
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2.3.1.1.2.2 The Export Data (CSV, TAB, or TXT Format) option creates a file in Comma Separated Value (*.csv), Tab Separated (*.tab), or Text File (*.txt) formats.



2.3.1.1.2.2.1 The CSV, TAB, or TXT Format Data can be exported by using the Select by Data and Time Range option and then selecting the range to export.





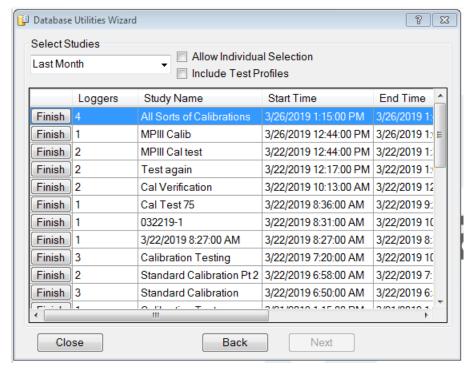
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2.3.1.1.2.2.2

The CSV, TAB, or TXT Format Data can also be exported by using the Select from Studies option and the selecting the Study to export.

The range of the Studies that are displayed can be selected from the Drop Down Menu.

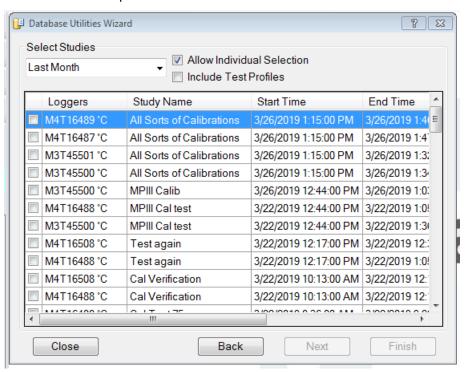




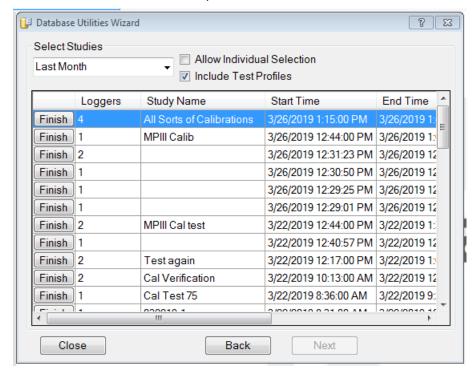
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When using the Select from Studies option the user can export data for individual Data Loggers used in a study by selecting the Allow Individual Selection option.



Test profiles can be exported by selecting the Include Test Profiles option.



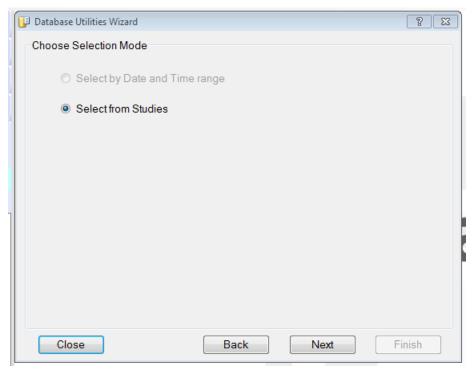


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2.3.1.1.2.3 Using the Export Data (Single File Per Data Logger "DPT" Format) creates a file in The DPT format and is included in the DT Pro software for backward compatibility for DTW style Data Loggers.

2.3.1.1.2.3.1 DPT Format Data can only be exported using the Select from Studies option.

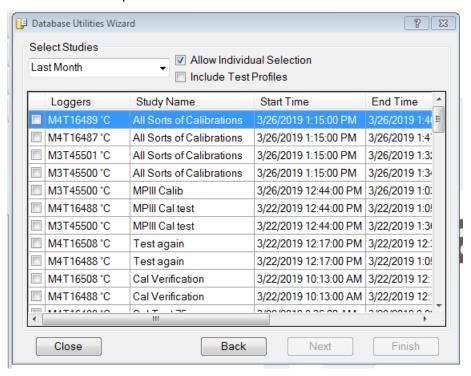




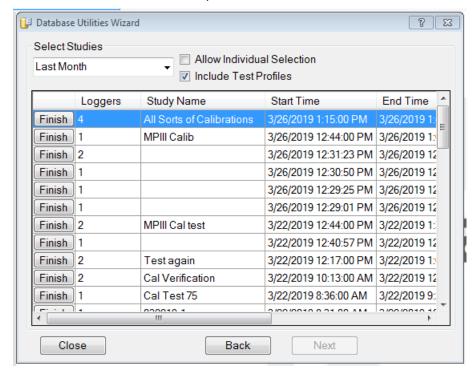
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When using the Select from Studies option the user can export data for individual Data Loggers used in a study by selecting the Allow Individual Selection option.



Test profiles can be exported by selecting the Include Test Profiles option.





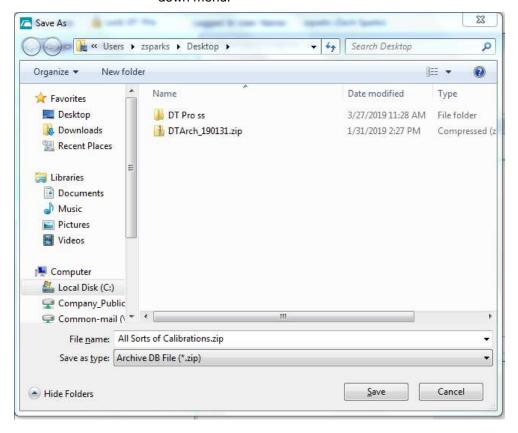
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2.3.1.1.2.4 Click the Finish button to create the archive.

When Exporting Archive, CSV, TAB, or TXT Formats, a Save As window will open and the file name used and the location where the file will be saved can be selected.

For CSV, TAB, or TXT files, the file type that the file is saved as can be selected from the Save as Type drop down menu.

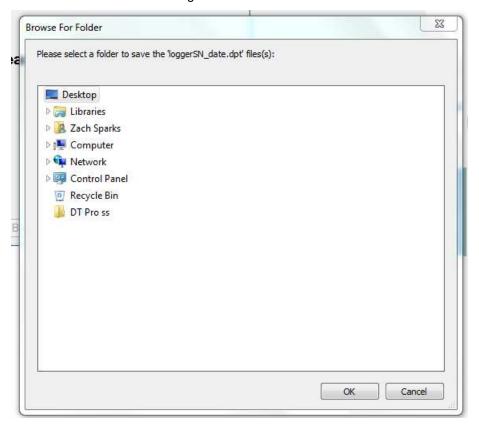




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When Exporting DPT Formats, a window will open and the Folder where the file will be saved can be selected. A file will be created for each Data Logger in the selected Study, and the file name cannot be changed.





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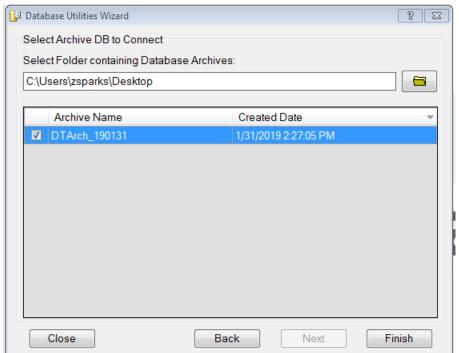
2.3.1.2 View Archive

Opens an archive file for viewing or report printing using the standard data view window.

Select the View Archive option and click "Next" button. A list of available archive files will be displayed. If the archives were not saved in the same location it will be necessary to browse to the folder where the archive files are saved. Select the desired archive and click "Finish" button.

A window will open asking if the user wants to use the existing Report Templates instead of the templates in the Archive file. Selecting Yes will not display the Archived Report Templates and Selecting No will only show the Archived Report Templates.





When an archive is opened, data from the archive file is not imported into the active database as this might overwrite existing configuration information. Instead, the connection to the standard database is suspended and replaced by a connection to the archive file.



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The archived files can then be viewed using the Reports Menu, refer to Section 5.1.3 for additional details.

The status of the connection to the Archive file is shown on the top menu bar. When finished with the archive, close the connection to the archive file using

at the top of the window. The connection to the standard database will be resumed.

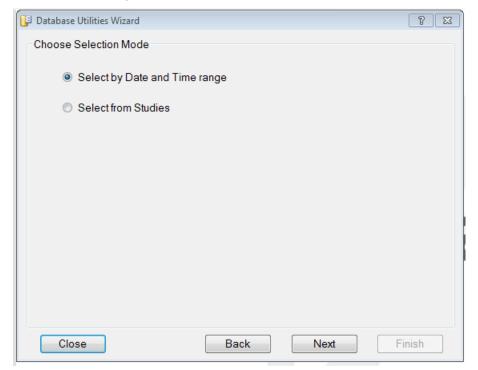
While viewing an archive, Data Logger functions, RF reception and some other system configuration items will not be available.

2.3.1.3 Delete

Prior to deleting any data, refer to your company procedures for records retention requirements.

The Delete option is available only to the DT Pro system administrators.

Select the Delete option and click the "Next" button.

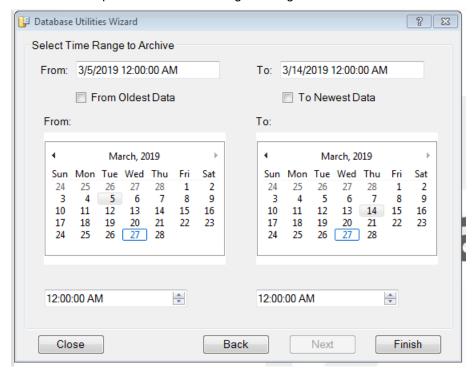




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2.3.1.3.1 Data can be deleted by using the Select by Data and Time Range option and then selecting the range of data to Delete.

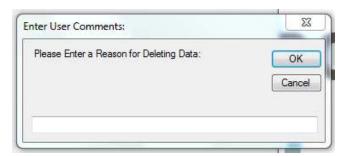


Selecting the "From Oldest Data" option will delete all data up to the Time and Data selected in the "To" fields.

Selecting the "To Newest Data" option will delete all data from the selected "From" Time and Date to the last data recorded by the software.

Selecting both the "From Oldest Data" and the "To Newest Data" options will delete all data in the DT Pro software.

When all selections have been made, click the "Finish" button. A window will open asking for a reason the data was deleted. A reason is not required to be entered to complete the data deletion.



Pressing Cancel will stop the data deletion process.

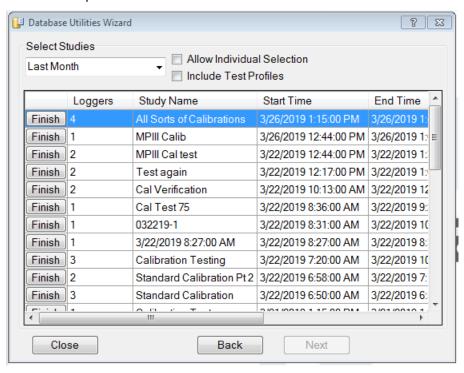


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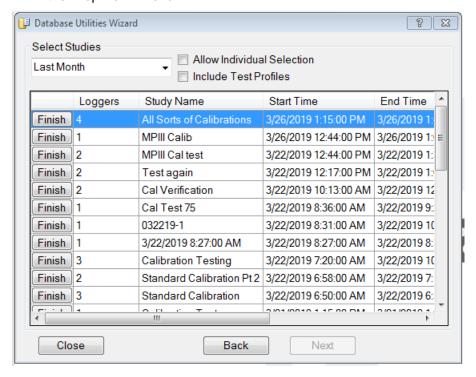
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2.3.1.3.2 Data can also be exported by using the Select from Studies option and the selecting the Study to export.

The range of the Studies that are displayed can be selected from the Drop Down Menu.



The range of the Studies that are displayed can be selected from the Drop Down Menu.

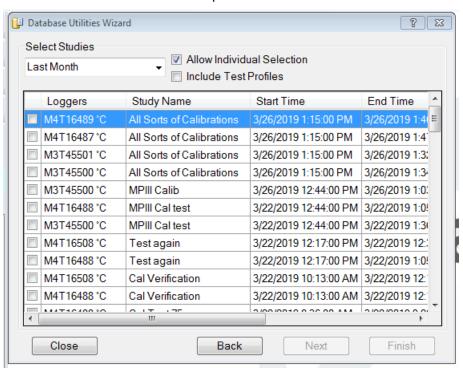




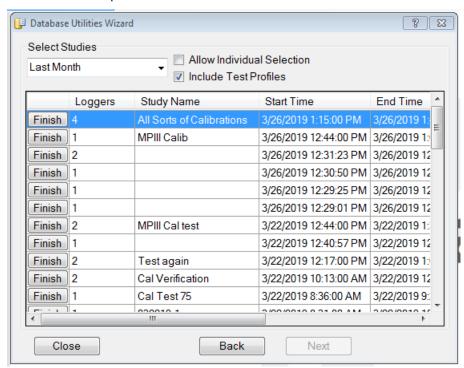
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When using the Select from Studies option the user can delete data for individual Data Loggers used in a study by selecting the Allow Individual Selection option.



Test profiles can be deleted by selecting the Include Test Profiles option.

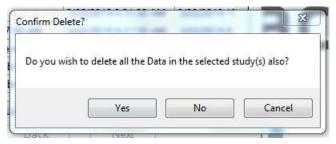




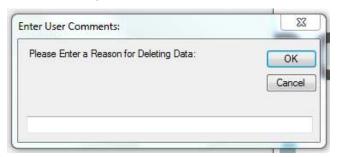
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Clicking on the Finish button for a selection will open a window to confirm the deletion of the data included in the Study. Select Yes to delete the data, or select No to only delete the Study, or Cancel to stop the deletion process.



Selecting the Yes or No option will open a window asking for a reason the data was deleted. A reason is not required to be entered to complete the data deletion.



Notes:

- In a LAN environment, Archiving and Report Template exporting are restricted to the host computer (i.e. the physical location of the database) only.
- When data is exported for use by other applications, the subsequent work output from these applications may not be 21 CFR Part 11 compliant.
- The performance of the DT Pro database (e.g. the time it takes to retrieve data or run a report)
 is dependent on the amount of data in the database. Archiving older data can increase the
 performance of DT Pro.
- It is highly recommended that the DT Pro database be periodically archived. DT Pro archive
 files contains measured data, a copy of the system configuration, Data Logger Tags (which
 may have changed over time), alarm setpoints, alarm histories, study definitions, audit trail
 entries and additional information at the time the file was created.

2.4 Database Configuration

Left click on the Configuration Tools menu, and then click on Database Configuration. The Database Configuration Utilities window will be displayed.

Database Configuration Utilities contains the tools required to set various database parameters such as physical location or local only versus shared (LAN) operation. It also contains diagnostic, recovery and backup tools.

Access to Database Configuration is not available while RF data reception is active.

2.4.1 Current Data Server Name

This box displays the name of the computer where data and security information is being stored. This can be the name of the local computer or of a network server.



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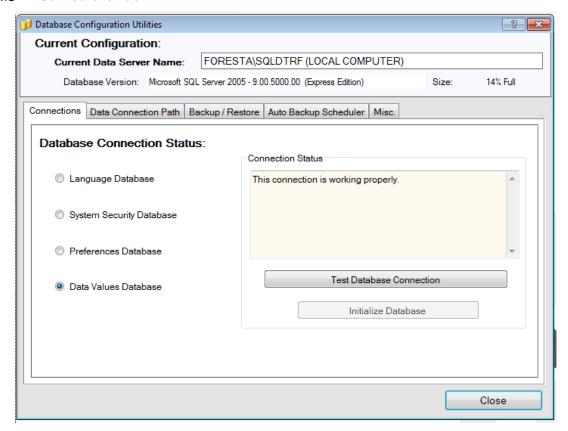
2.4.2 Database Version

The current Database Version is displayed along with the current size of the Database.



Database Configuration Utilities contains four tabs:

2.4.3 Connections Tab



The DataTrace Pro database is composed of four distinct databases which are listed in the Connections Tab. The status of the connection to each of these can be reviewed, tested, or initialized.

The specific database functions are:

2.4.3.1 Language Database

Provides translation and localization services. **The Language Database is machine specific.**

2.4.3.2 System Security Database

Contains all security related settings and information (including the audit trail). The System Security Database is located on the computer listed as the Current Data Server Name.



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2.4.3.3 Preferences Database

Contains user preferences such as units of measure, graph line colors, report templates, etc. **The Preference Database is machine specific.**

2.4.3.4 Data Values Database

Contains logged data, calibration information, group, and alarm definitions, etc. The Data Values Database is located on the computer listed as the Current Data Server Name.

If there is a problem with the connection to any one of these databases, it will be indicated by a yellow warning icon in the Connection Status window.

2.4.3.5 Test Database Connection

Select a database and click the Test Database Connection button to refresh the connection status text box. The test routine can resolve a problem or indicate that initialization is required.

2.4.3.6 Initialize Database button:

Use this button if the result of Test Database Connection indicated it is needed.

Note:

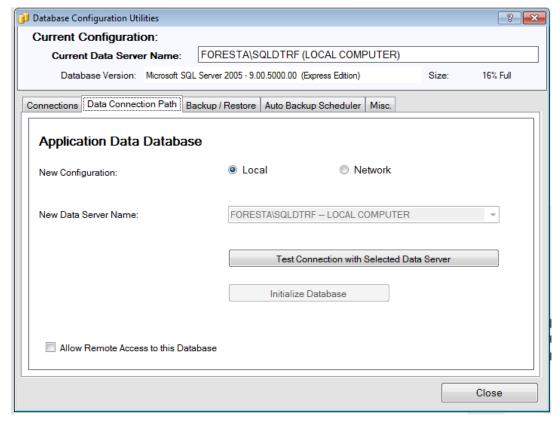
 Report Templates and other user preference settings exist only on the local computer and are not shared across a network. This allows the system administrator to decide which reports templates will be available at specific computers, and to customize the settings of each computer to the needs of its user. If report template sharing is desired, refer to Section 0 for details on how to export the desired template and import it on the new computer.



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2.4.4 Data Connection Path Tab



The Data Connection Path Tab allows the system administrator to configure the physical location of the Data Value and System Security databases and set the sharing option.

2.4.4.1 Local

Select this option for local computer data and security information storage. This is the default setting.

2.4.4.2 Network

Select this option for remote (LAN network) computer data and security information storage. When selected, the Data Server Name box will be enabled and display the available remote connections.

In order to setup a shared network or remote connection, the DT Pro LAN Server edition must be installed on the computer or server where data will reside, and the Allow Remote Access option must be selected before remote computers can connect to it.

2.4.4.2.1 Test Connection

When switching between Local or Network, or between different Data Servers, always Test the Connection with the selected Data Server.

2.4.4.2.2 Initialize Database

Use this option if the connection test result indicates it is needed.



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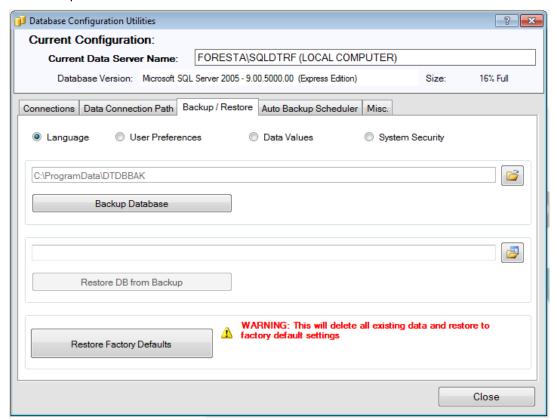
2.4.4.3 Allow Remote Access

Available only if the Local option has been selected while using the DT Pro LAN Server edition. Selecting this box will display the local data and security database to remote computers. The name of the connection is shown and is what will appear as an available selection in the Data Server Name box for remote computers.

Notes:

- It is possible to manage data by changing the data connections (have local data for some tests or studies, network / shared data for others); however, utilities do not exist for synchronization or data exchange between different network or local databases (other than the manual archive / restore archive process).
- It is possible for other SQL compatible applications (e.g. Crystal Reports or Microsoft Excel) to access data directly from the DT Pro database. Mesa Laboratories, Inc. can provide guidance on utilizing this functionality.

2.4.5 Backup/Restore Tab



The Backup/Restore Tab provides disaster recovery tools. These procedures are applicable only to the local databases; should they be required for a remote (network) database, they must be executed at that computer. The procedures are executed individually for each of the four databases as needed based on the selection made.

It can be difficult to back up the DT Pro SQL databases using external tools or software while DT Pro has a live connection to the databases. If backup to external drives or other media is desired, it will in general be easier to use this backup process to create a copy of the databases to which there is no live connection, and then secure the copy as desired. This process can also be automated, refer to Section 0 for additional details.



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2.4.5.1 Backup Database

Creates a copy of the database and saves it at the displayed location.

Use the folder button to change the save location. Backup file extensions are type *.zip; the file name indicates the database type (in English) and date of creation.

2.4.5.2 Restore DB from Backup

Use the folder button to select an appropriate backup file and click the Restore button.

This option is typically used in cases of database damage or corruption and Mesa Laboratories Inc. should be consulted prior to Restoring the Database.

Data that is newer than the backup creation date will be lost!

2.4.5.3 Restore Factory Defaults

Removes all existing data will be lost and return the DT Pro software as if it had been just installed.

Notes:

 The severity of data loss associated with restoring from a backup or factory defaults, and implications on data retention or 21 CFR Part 11 compliance are dependent on the selected database.

Restoring the Language or User Preference has minimal implications (possibly only require resetting a few preferences). Restoring the System Security database on the other hand entails the loss of audit trail information. In regulated environments, the user should document the cause and details of any restoration.

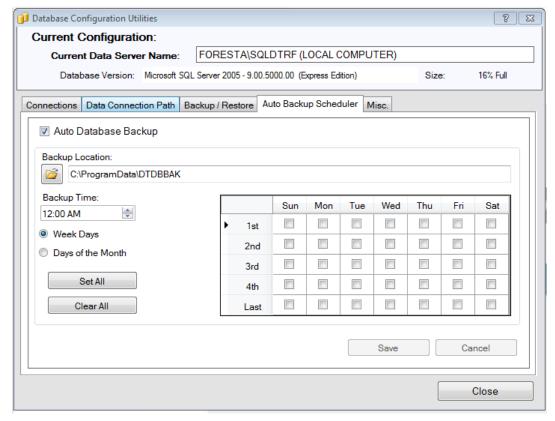
 If the DT Pro software is upgraded to a different version, backups should be performed immediately after the upgrade so as to assure backup file compatibility.



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2.4.6 Auto Backup Scheduler Tab



DT Pro can be configured to automatically perform a complete database backup at defined times. The Auto Backup Scheduler Tab allows the administrator to enable or disable this feature using the top left check box.

If Auto Database Backup is enabled, the databases will be backed up always using the same file names, at the specified location. Old backup files will be overwritten. There is no live database connection to the backup files. The backup files are in *.zip format, and can be secured (e.g. tape backup) or copied to different location

The following items are required in order to enable Auto Backup:

2.4.6.1 Backup Location

Enter a path or browse to the folder where the backup files will be saved.

2.4.6.2 Backup Time

Select the time of day that the backup will be performed. This should be some time when system usage is expected to be low (e.g. near midnight).

2.4.6.3 Week Days

Use this option to define the backup schedule by the day of the week (e.g. each Friday, or every other Monday). Place a check mark for each day that a backup will be completed.

Options are also provided to select or un-select all.



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2.4.6.4 Days of Month

Use this option to define the backup schedule based on absolute dates within a month (e.g. on the first and 15th day of the month). An option is also provided to include the Last Day of the Month.

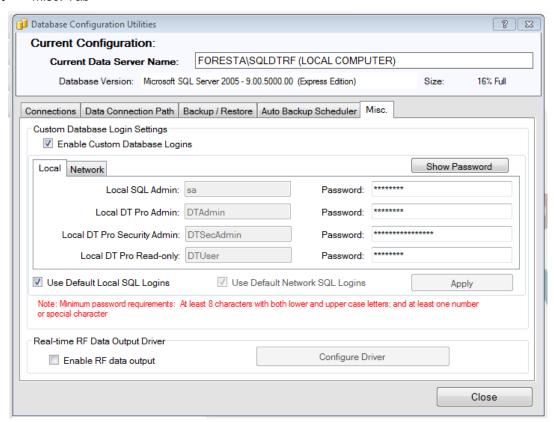
Options are also provided to select or un-select all.

Once the desired selections have been made, click the Save button to apply the changes. The next scheduled backup date and time will be displayed at the lower left corner.

Notes:

- The backup process can require a few minutes. During this time RF data reception is disabled. While any lost data will be recovered, it is preferable to select a backup time when RF communication is not expected.
- The backup process will only occur if DT Pro is running.

2.4.7 Misc. Tab



2.4.7.1 Enable Custom Database Logins

Custom Database logins can be setup for both Local and Network Databases. The Database passwords must be a minimum of 8 characters in length, contain both upper and lower case letters and must have at least one number or special character.

2.4.7.1.1 The option to use the Default Local SQL Login or Default Network SQL Logins can be selected.



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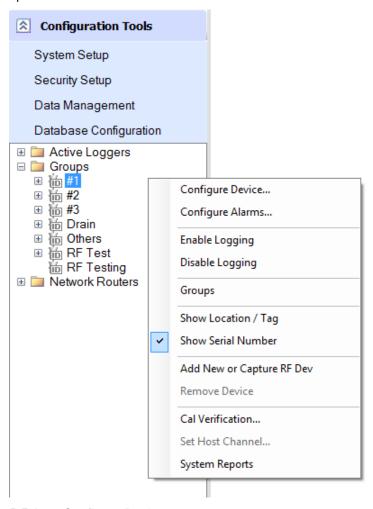
2.4.7.2 Enable RF data output

The Enable RF data output is a customizable option that can be used to transfer data from DT Pro to other electronic systems or databases.

On standard systems, this option does not perform any functions. Contact DataTrace Technical Service team for additional details on Enabling RF data output.

2.5 Additional Configuration Tools Menu Options

Right clicking on the white area in the Configuration Tools Menu displays additional configuration options for DT Pro.



2.5.1 Configure Device

The Devices (Data Loggers and Network Repeaters) used by the DT Pro software can be setup to allow the user flexibility in how the software handles the devices when performing studies and preparing reports.

Right Clicking on a Device, Group Name, or the blank area of the Configuration Tools menu and selecting Configure Device will open the Device Configuration Window.

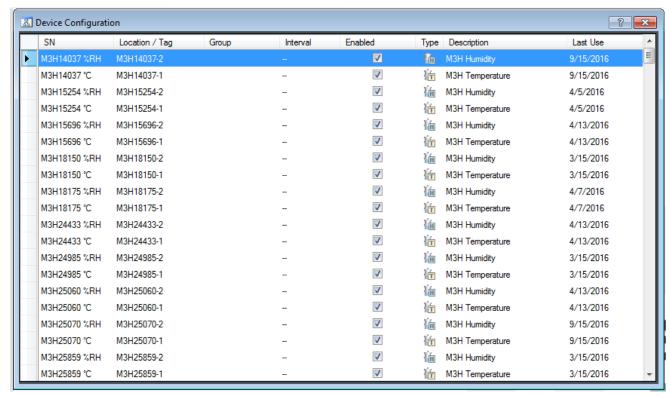
The Device Configuration window allows configuration of the selected Data Loggers and can be sorted in ascending or descending order by clicking on the column title.



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While the Device Configuration window is open, selecting a different Data Logger or Group will display the information for the selected items.



2.5.1.1 SN

The Serial Number for each device is listed as a reference and cannot be modified.

2.5.1.2 Location/Tag

The DT Pro software treats each measurement as a unique entity. Each measurement or channel from a Data Logger with more than one channel (e.g. a pressure / temperature Data Logger) is treated separately, and the user can assign a unique identifier to the device channel.

This identifier could represent a location, an equipment number, or any other identifier that the user decides upon. Additionally, the user can organize the Data Loggers or monitors into Groups and assign any desired name to the Group. The DT Pro software allows the user to generate Reports, Summaries or Graphs by group, refer to Sections 5.1.3, 5.2.1, and 0 for additional details.

The Location or Tag for a device can be edited by selecting the Location/Tag column cell for the device and entering the new Location or Tag information.

The Location/Tag can also be displayed in the Report, refer to Section 5.2.5.1 for additional details.

2.5.1.3 Group

A Device can be added to a Group by selecting the Group column for the Device and selecting the Group form the menu.

A new group can be created by selecting the Add New Group option.



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2.5.1.4 Interval

The data logging interval setting can be changed for monitors and MPRF Data Loggers.

Warning:

Changing a Data Logger's interval dynamically (using this method as opposed to programming the Data Logger) can result in data loss.

If the Data Logger was programmed using the "Never Stop" option the Data Logger is operating identical to an environmental monitor and changing interval dynamically will not be an issue, refer to Section 3.1 for additional details.

If the Data Logger was programmed using the "Stop When Full" option, changing the interval dynamically will also reset the Data Logger start time; it will be the time the command was received rounded up to whole minutes. If data is subsequently downloaded from the Data Logger, the data will start at this new time, not at the original programmed time.

2.5.1.5 Enabled

The default condition is enabled or checked. When disabled (no check mark) all data, whether received by RF or read from a Data Logger, will be discarded, and not stored in the database.

2.5.1.6 Type

The Data Logger measurement type is indicated by a T for temperature, H for relative humidity, or P for pressure.

2.5.1.7 Description

User can enter any descriptive information (e.g. tolerances or calibration information. This description can optionally be included in a report, refer to Section 0 for additional details.

2.5.1.8 Last Use

The date that the Data Logger was last used (programmed, read, or tested) is listed.

2.5.2 Configure Alarms

The DT Pro alarm functions are applicable only to MPRF Data Loggers using the DT Pro Sentinel, Plus or LAN Server editions of the software.

As data is received via RF, it is evaluated per the defined alarm settings. Historical or download data is not evaluated. If an alarm is generated, the result is displayed via an icon in the Wireless Data menu. If notification defined the specified personnel will be notified when an alarm condition occurs.

2.5.2.1 Alarm Setup

Right Clicking on a Data Logger or Group in the Configuration Tools menu and selecting Configure Alarms will open the Device Alarm Configuration Window.

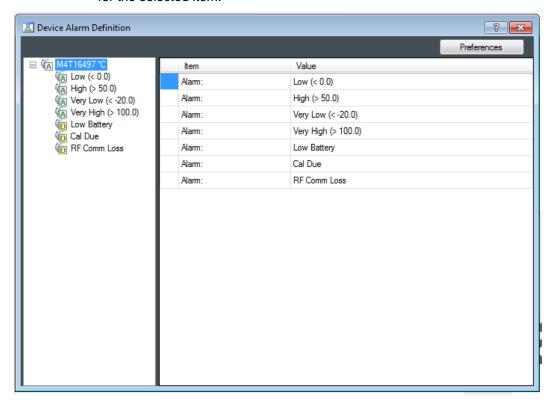
The DT Pro Alarm Configuration window is split into two sections. On the left are the selected Data Loggers. On the right is the list of all alarms for the Data Logger or the properties for a selected alarm.



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While the Device Alarm Definition window is open, clicking on a different Data Logger or Group in the Configuration Toole menus will display the Alarm setup for the selected item.



2.5.2.2 Adding an Alarm

Select a Data Logger, right click to bring up options menu, select Add Alarm, and then choose the alarm type. A window will open where the setpoint for the alarm must be entered (if required).

2.5.2.3 Alarm Types

2.5.2.3.1 Very High and High

An Alarm is triggered when the measured value is greater than the alarm set point.

2.5.2.3.2 Very Low and Low

An Alarm is triggered when the measured value is less than the alarm set point.

2.5.2.3.3 Low Battery

A Warning is triggered if battery level falls below 10%, and an Alarm is triggered at battery level 0%.

2.5.2.3.4 Cal Due

The user defines the calibration due date, a warning is issued one week before this date, and an Alarm is raised if Cal due date is reached.



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2.5.2.3.5 Comm. Loss

Alarm is raised if RF communication is not received for eight data logging intervals or 10 minutes (whichever is greater).

2.5.2.4 Alarm Properties

| | Item | Value |
|-----------|----------------------------------|---------------------------------|
| A | Type: | Very High |
| 6 | Status | Disabled |
| | Setpoint: | 100.0 |
| | Allowed Excursion Time (minutes) | 0 |
| | Recovery Setpoint | 100.0 |
| \bowtie | Contact: | NONE |
| | Recover Mode | Manual (Require Acknowledgment) |
| ₩ | Escalation: | NONE |
| | | |

Clicking on a property value will open a window to edit the property (except for Alarm Type). Properties applicable to the selected Alarm will be displayed.

2.5.2.4.1 Status

An alarm can be Enabled or Disabled . Disabled alarms are not evaluated. Alarms are disabled by default.

2.5.2.4.2 Set Point

The value which must be exceeded for an Alarm to be activated. Calibration Due Date replaces set point for the Cal Due Alarm type.

2.5.2.4.3 Allowed Excursion Time

An alarm is delayed until the set point has been exceeded for at least this time.

2.5.2.4.4 Recovery Set Point

The value which must be exceeded before an alarm can be cleared. For High or Very High types, the recovery point must be less than the set point, and vice versa for Low and Very Low Alarms.

2.5.2.4.5 Contact

An e-mail can be sent to one or more of the system users.

2.5.2.4.6 Recover Mode

Controls how an alarm is cleared. An alarm can be cleared automatically (i.e. when the alarm condition no longer exists) or manually.



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2.5.2.4.7 Escalation

Available only if manual recovery is selected. An e-mail can be sent to a system user if an alarm is not acknowledged after a defined time.

2.5.2.4.7.1 Add Escalation Contact

Select the User who will receive the notification email if the alarm has not been acknowledged after the defined time has passed.

2.5.2.4.7.2 Set Escalation Time

The time before the escalation email is set can be defined by selecting this option. Must be set to a number of hours, and the default value is 1 hour.

2.5.2.4.7.3 Remove Escalation

Remove the Escalation Contact and set the Escalation Time to the default value.

2.5.2.5 Alarm Controls

The Left Side of the Device Alarm Definition Window shows:

- 2.5.2.5.1 Whether a Data Logger or monitor has an Alarm.
- 2.5.2.5.2 Whether an Alarm is Enabled or Disabled
- 2.5.2.5.3 Enabling or disabling can be performed for an individual Alarm, all the Alarms of one Data Logger, or the Alarms of the entire group.
- 2.5.2.5.4 Once an alarm is declared, it can be copied to another Data Logger or to the entire group by selecting the Alarm, right clicking on the Alarm, selecting Copy Alarm, and the right clicking on a different Data Logger and selecting Paste Alarm or Paste Alarm to Group.
- 2.5.2.5.5 Alarms can be removed individually, by Data Logger or by type for the entire group by

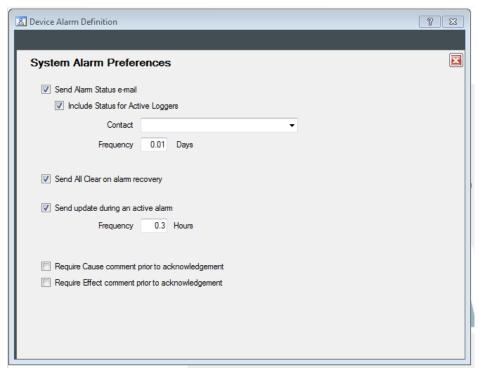


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2.5.2.6 Alarm Preferences

The Preferences button located at the top left of the Alarms window allows the user to customize alarm behavior. The selections apply to all defined alarms.



2.5.2.6.1 Send Alarm Status e-mail

If selected, a status email will be sent to the selected contact at the defined frequency.

Selecting the Include Status for Active Loggers option will send a status email for all active loggers even if no alarms have occurred.

2.5.2.6.2 Send All Clear on Alarm recovery

Does not apply to Low Battery or Cal Due alarm types

2.5.2.6.3 Send Update during an active alarm

Sends additional notifications for active alarms. Does not apply to Low Battery, Cal Due, or Comm Loss Alarm types

2.5.2.6.4 Require Cause comment prior to alarm acknowledgement

The user must enter a comment about the cause of the Alarm prior to acknowledging an alarm

2.5.2.6.5 Require Effect comment prior to alarm acknowledgement

The user must enter a comment about the potential effects of the Alarm prior to acknowledging an alarm



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2.5.2.7 Managing Alarms

- 2.5.2.7.1 If there is an active alarm event, an icon will be displayed on the Wireless Data menu.
- 2.5.2.7.2 If there is an active alarm event, and the Wireless Data menu is expanded, the icon of the Data Logger will change to indicate it as the alarm source.
- 2.5.2.7.3 Clicking on the Real Time view Alarm status column exposes alarm details.
- 2.5.2.7.4 Alarms which require manual recovery are acknowledged from within the alarm details.
- 2.5.2.7.5 In Reports, there is an option for to include an Alarm summary in the Report.

In Reports, an alarm event can optionally be used to generate phase or sub-summaries to facilitate deviation statistics.

Refer to Section 0 for additional details.

2.5.3 Enable/Disable Logging

- 2.5.3.1 Right Clicking on a Data Logger or Group menu and selecting Enable Logging will start the RF data transmission of the Data Logger or Group.
- 2.5.3.2 Right Clicking on a Data Logger or Group menu and selecting Disable Logging will stop the RF data transmission of the Data Logger or Group.

When logging is disabled all data, whether received by RF or read from the Data Logger, will be discarded, and not stored in the database.

2.5.4 Groups

2.5.4.1 Creating a New Group

- 2.5.4.1.1 Right click on the Configuration Tools menu and select the Groups option.
- 2.5.4.1.2 Selecting the Add New option will open a window where the new Group name can be entered. Clicking on Ok will create the Group.

Refer to Sections 2.5.1.3, 2.5.4, 3.1.7.5 and 4.4.3.1 for additional details on assigning Data Loggers to Groups.

2.5.4.2 Deleting an Existing Group:

A Group can only be deleted if there are no Data Loggers assigned to it. The simplest way to tell if there are still devices assigned to the selected group is to see if there is a $^{\boxdot}$ to the left of the group name. If there isn't one, then the Group is empty, and can be deleted.

- 2.5.4.2.1 Right click on the Configuration Tools menu and select the Groups option.
- 2.5.4.2.2 Select the Remove option to delete the Group.



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2.5.5 Show Location/Tag or Show Serial Number

The way that the Data Loggers are displayed in the Configuration menu can be set to either be by Location/Tag or by Serial Number.

The Location/Tag of a Data Logger can be changed if required, refer to Section 2.5.1.2 for additional details.

2.5.6 Add New or Capture RF Device

The Network Repeater (Repeater) is a RF Device that is used to receive a transmission from a Data Logger or a different Repeater, and then re-transmit it in order to extend communications range.

2.5.6.1 Repeater Setup

| 2.5.6.1.1 | Ensure the Repeater power is turned off. |
|-----------|---|
| 2.5.6.1.2 | Enable RF Reception on the desired Channel by clicking on the |
| | in the Wireless Data menu, refer to Section 0 for additional details. |
| 2.5.6.1.3 | From the Configuration Tools menu , select the Network Routers folder, and right click on the menu to display the options menu. |
| 2.5.6.1.4 | Select "Add New or Capture RF Device". Enter the Serial Number of the repeater when prompted. |
| 2.5.6.1.5 | Place the Repeater close to the MPRF PC Interface (5 to 30 feet). |
| 2.5.6.1.6 | Plug in, turn on or place battery into the repeater to power it up. |
| 2.5.6.1.7 | The Repeater will scan all channels looking for a MPRF PC Interface. Verify that it appears within the Wireless Data menu. |

Notes:

- This procedure requires that RF reception be enabled prior to powering
 up the Repeater so as to prepare the MPRF PC Interface to issue a
 special command to the repeater as it performs its start-up scan of all
 channels. When turning on the repeater, the red LED will blink for each
 channel it scans. If the procedure fails, is interrupted or the blinking LED is
 not observed, turn the power off and then back on.
- This procedure sets and locks the RF channel for the device and establishes the current computer as the RF destination and does not need to be repeated if the Repeater is powered off. To change the RF channel or use the device on a different computer, re-execute this procedure with the MPRF PC Interface set to the desired channel, refer to Sections 3.1.7.7 and 3.3.6.3 for additional details.
- If the device was previously added to the DT Pro software, but has been configured for a different RF channel, or a different computer, perform this procedure. For ease, right clicking on the Repeater and selecting the "Add New or Capture RF Device" will pre-populate the serial number.

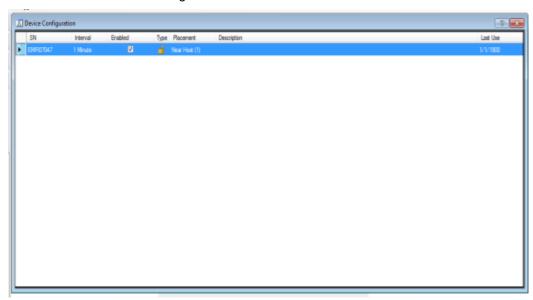


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2.5.6.2 Repeater Configuration

2.5.6.2.1 From the Configuration Tools menu, right click on the Repeater and select the Configure Device option. If the Repeater has not been added to the DT Pro software refer to Section 2.5.6 for details on adding the new RF Device.



2.5.6.2.2 Click on the Interval column and select the desired data logging interval.

The preferred setting for repeaters is either 1 minute or equal to the logging interval of Data Loggers, whichever is greater.

The interval setting can be changed at any time.

2.5.6.2.3 Enabled

The default condition is enabled or checked. When disabled (no check mark) the Repeater will not transmit RF data.

2.5.6.2.4 The Repeater Function setting to will be displayed in the Type column and is set in the Tools menu of the Logger Functions menu. The Repeater must be connected to the using the Network Repeater Interface Cable in order to change the function/type setting. Refer to Section 3.3.6.4 for additional details.

The Standard Repeater Function is shown as



and the

Dedicated Repeater Function is displayed as



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2.5.6.2.5 Click on the Placement column, from the menu that appears, set whether the Repeater will be near the host (within 150 ft.), a medium distance from the host (150 - 300 ft.), far from the host (≥ 300 ft.), or other.

If other is selected the user will be prompted to enter the Minimum Level (distance) that the Repeater will be placed.

The placement setting is used by the mesh network system to efficiently route data toward the MPRF PC Interface; the setting established a preferential (but not absolute) direction from far to near to host.

In general, if there are a large number of Repeaters, it is best to have \leq 4 Repeaters set as Near and \leq 8 Repeaters set as Medium, all other Repeaters should be set to Far (even if they are close to the host).

2.5.6.3 MPRF PC Interface Setup

- 2.5.6.3.1 Right click on the Configuration Tools menu and select "Add New or Capture RF Device". Enter the Serial Number of the MPRF PC Interface when prompted.
- 2.5.6.3.2 The MPRF PC Interface will now be displayed in the Network Routers folder.

2.5.6.4 Deleting a RF Device

- 2.5.6.4.1 Right click on the RF Device to be deleted from the Network Routers folder.
- 2.5.6.4.2 Select the Remove Device option from the menu to delete the RF Device.

2.5.7 Cal. Verification.

A calibration verification can be completed on a Data Logger or Group by right clicking on the Data Logger or Group and selecting the Cal Verification option.

Refer to Section 0 for additional details about Calibrations.

2.5.8 Set Host Channel

The RF Channel used by a MPRF PC Interface can be set or updated by right clicking on the MPRF PC Interface in the Network Routers folder and selecting the Set Host Channel option.

A window will open where the RF Channel that will be used by the MPRF PC Interface can be entered.

2.5.9 System Reports

2.5.9.1 Setup

The Workstation Setup Report provides details on the local computer installation and setup, Wireless radio settings (if applicable), User Preferences, and Calculation parameters.

To view or print the Workstation Setup Report right click anywhere in the blank area of Configuration Tools, select System Reports, and then select Setup.



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2.5.9.2 Security

The System Security Report provides details on the Security Settings, User Accounts, and Email Configuration.

To view or print the System Security Report right click anywhere in the blank area of Configuration Tools, select System Reports, and then select Security.

2.5.9.3 Configuration

The System Configuration Report provides details on Device Group Assignment, Serial number, Locations, Logging Interval, and Description.

To view or print the System Configuration Report right click anywhere in the blank area of Configuration Tools, select System Reports, and then select Configuration.

2.5.9.4 Alarms

The Alarm Definitions Report provides details on the defined alarms for each Data Logger.

To view or print the Alarm Definitions Report right click anywhere in the blank area of Configuration Tools, select System Reports, and then select Alarms.



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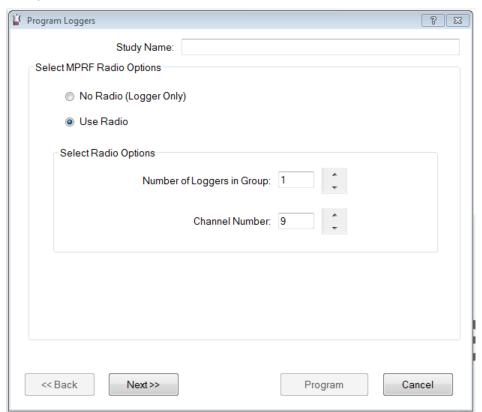
3.0 LOGGER FUNCTIONS MENU

3.1 Programming Data Loggers

Before a Data Logger can be used, it must be programmed. The act of programming a Data Logger tells the Data Logger when you want it start logging data (start time) and how fast you want the data to be logged (interval).

In addition, you can program other parameters for the Data Logger to help in the logging or transmitting of data for MPRF Data Loggers.

3.1.1 Select Program from the Logger Functions menu. The Program Loggers window will open.



- 3.1.2 You can define a Study Name in the top box at any time before the logger is programmed.
 Note:
 - If a study name is not defined or a duplicate study name is used, a study is still
 created and will be named according to the programmed start time in the Wireless
 Data and Reports menus.
- 3.1.3 MPRF Radio Options
 - 3.1.3.1 No Radio

The Data Loggers will not transmit data using RF. All data is stored on the Data Logger and must be read from the Data Logger, refer to Section 3.2 for additional details.



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3.1.3.2 Use Radio

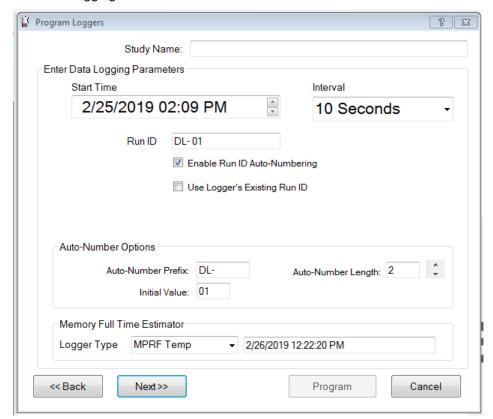
The Data Loggers will transmit data using RF. Data is also stored on the Data Logger

3.1.3.2.1 Enter the number of Data Loggers that will be programmed and the RF Channel Number that will be used.

Note:

- If the system has been configured to not use Wireless, this screen will not be displayed. Refer to Section 2.1.1.2 for additional details.
- Lower RF Channel numbers provide slightly higher power capability and longer range than higher numbered RF Channels

3.1.4 Data Logging Parameters



3.1.4.1 Start Time

The date and time that data logging will begin.

The initial time displayed is defined by the Default Start Time boundary, refer to Sections 2.1.3.1.1 and 2.1.3.1.2 for additional details.

3.1.4.2 Interval

Defines how often data will be acquired. The logging interval can be set at 1 second, 2 seconds, 5 seconds, 10 seconds, 15 seconds, 20 seconds, 30 seconds, 1 minute, 2 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes or 1 hour.



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3.1.4.3 Run ID

An optional 8 character process identifier which will be stored in the Data Logger.

3.1.4.4 Using Run ID Auto-Numbering

The numeric portion of the Run ID will increment automatically for each Data Logger based on the selected options.

3.1.4.4.1 Auto-Number Prefix

The Prefix used for each Data Logger can be set. The Prefix can be a maximum of 8 characters in length.

3.1.4.4.2 Auto-Number Length

The number of digits in the Data Logger Run ID can be set. The Auto-Number Length can be 1-4 digits.

3.1.4.4.3 Initial Value

The first number assigned can be set. The number can be set from 0 to 9999.

3.1.4.5 Using Logger's Existing Run ID

The Run ID that was last used for the Data Logger will not be used and a new Run ID will not be assigned.

Notes:

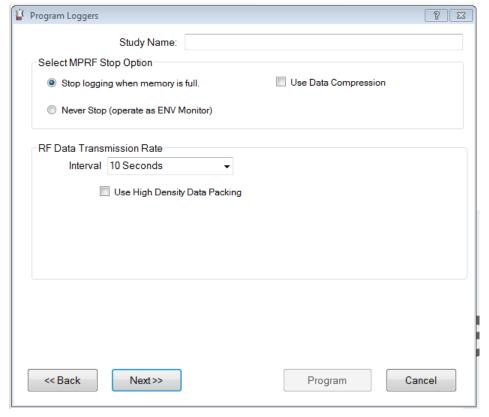
The Logger Type and Memory Full Time boxes at the bottom show when each type
of Data Logger will stop recording data based on the selected Start Time and
Interval.



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3.1.5 MPRF Stop Options



Notes:

- If your system has been configured to not use Wireless, this screen will not be displayed. Refer to Section 2.1.1 for additional details.
- These options only apply to MPRF Data Loggers.
- 3.1.5.1 Stop logging when memory is Full

The Data Logger(s) will record data points until the capacity is reached (typically 8000 data points for a single channel Data Logger).

3.1.5.2 Use Data Compression

This option is only visible when the Stop logging when memory is Full option is selected.

When selected, a MPRF Data Logger with version "T" or newer firmware can log twice as many data points as normal (typically 16,000 pts. for a single channel Data Logger) by compressing the logged data. Compressed data is limited to two decimal places of resolution.

3.1.5.3 Never Stop

Logged data is limited to 1536 time stamped points, newer data replaces the oldest data once 1536 points have been logged.



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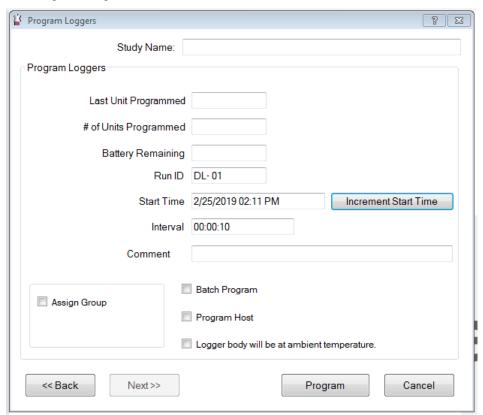
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3.1.6 RF Data Transmission Rate

Notes:

- If the No Radio option is selected this option will not be displayed.
- 3.1.6.1 Each MPRF Data Logger requires a specific time slot for communications to occur after the Data Logger logs data. This time slot is assigned automatically by DT Pro. Normally, two Data Loggers can communicate data within 1 second, in High Density Data Packing mode; four Data Loggers can communicate per second. The total amount of data points that can be reliably communicated depends both on the total number of Data Loggers and the data logging intervals of the Data Loggers.
- 3.1.6.2 The RF protocol used allows for the retrieval of any missed data points. It is possible to have a group of Data Loggers sampling at short intervals that acquire data faster than it can be transmitted. This situation will be indicated in the RF data transmission rate status box.
- 3.1.6.3 From the number of Data Loggers being programmed, the selected interval, records or RF receptions from other active Data Loggers, DT Pro determines a minimum allowed data transmission interval using standard data packing. High Density Data Packing can be selected to allow a reduced transmission interval, but there will be a decrease in RF communication reliability.

3.1.7 Programming Procedure



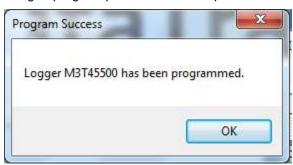
- 3.1.7.1 Place a Data Logger in the PC Interface.
- 3.1.7.2 If desired, enter or change the Run ID to be loaded in this Data Logger.
- 3.1.7.3 Click the Program button.



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3.1.7.4 Remove the Data Logger from the PC interface when the screen indicates the loading of program parameters is complete.



The message that indicates programming success can be disabled in the system setup.

Sounds can be used to indicate programming success or failure if selected in the system setup Programming a Data Logger which has not had its current data downloaded will result in a warning message; this message can be disabled in the system setup.

3.1.7.5 Assign Group

If the Allow Group assignment at Program Time option was selected, the Data Loggers can be added to existing Groups during Programming. Select the Assign Group option, and then select the Group the Data Logger will be added to from the drop down menu. Refer to Section 2.1.3 for additional details.

3.1.7.6 Batch Program

If selected, when "Program" is clicked, an automated detection process will start, and the "Program" button will change to "Stop". When the programming parameters have been loaded in the Data Logger, remove the Data Logger from the PC Interface, and place another Data Logger in the PC Interface. It will be loaded without need for further button clicks.

3.1.7.7 Program Host

Select this option if a different channel was chosen in a previous step, or if it is the first time the MPRF PC Interface is being used. The entered channel will be loaded into the MPRF PC Interface.

If Program Host is not selected, a warning message will be displayed in the event that the selected RF channel does not match the Host's current channel.

3.1.7.8 Logger body will be at ambient temperature.

Select this to improve RF performance if the measured temperature will be very hot or cold, but the body of the Data Logger will be near ambient temperature (does not apply to MPIII models).

3.1.7.9 User Comment

Prior to programming, a comment can be entered. This comment will be associated with the programmed Data Logger and be visible in the program and other reports. It will also be visible when the Data Logger is read and can be edited (or entered) either at that time or in the final report. Refer to Section 5.2.1 for additional details.



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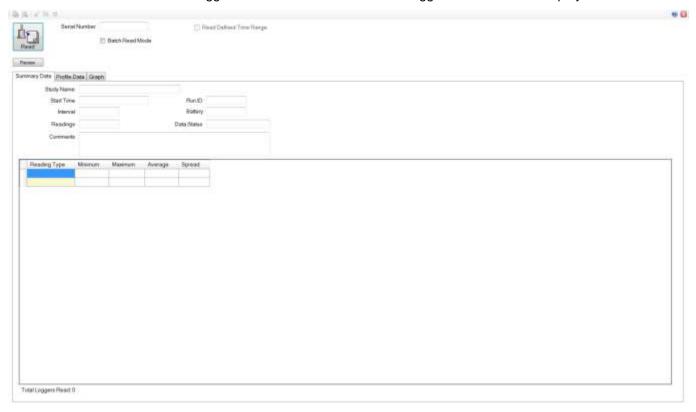
The comment is not loaded into the Data Logger, it remains on the computer used to program the Data Logger. If the Data Logger is read on a different computer, the User Comment will not be available.

Notes

• In the event the start time elapses before all Data Loggers have been programmed, an "Increment Start Time" button will appear. Using it will increment the start time by the selected interval, assuring that logged data can be aligned in grid format for reports.

3.2 Reading Data Loggers

Select Read from the Logger Functions menu. The Read Loggers screen will be displayed.



3.2.1 Standard Read

- 3.2.1.1 Place the Data Logger in the PC Interface.
- 3.2.1.2 Click the "Read" button.
- 3.2.1.3 When download is complete, view the Data Logger data.
- 3.2.1.4 To read another Data Logger, place next Data Logger in the PC Interface and click "Read".



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3.2.2 Batch Read

To enable batch Read mode, make sure the "Batch Read Mode" option is selected prior to reading the first Data Logger.

- 3.2.2.1 Place a Data Logger in the PC Interface.
- 3.2.2.2 Click the "Read" button.
- 3.2.2.3 When download is complete, remove the Data Logger from the PC Interface
- 3.2.2.4 Place next Data Logger in the PC Interface; it will be detected and downloaded automatically.
- 3.2.2.5 When all Data Loggers have been read, click "Stop".

3.2.3 Reading a Specified Time Range

The following options and associated controls will be available or visible only if the "Allow Read Preview and Time Range Selection" preference has been enabled in the System Setup.

3.2.3.1 Preview

Same as Standard Read; however, the data is **NOT** saved in the database. The data can be reviewed, and the desired time range determined. Data acquisition is stopped.

3.2.3.2 Read Defined Time Range



Serial Number M4H15992

Batch Read Mode

Read Defined Time Range

*

From 03/01/2019 08:20:00 AM

To 03/01/2019 08:30:30 AM

Preview

When selected, only data that falls within the From and To date time fields will be downloaded and saved. This selection is available only after a Data Logger has been read or previewed. The option must be set prior to setting the range values and can only be set after previewing or reading a Data Logger.

3.2.3.2.1 Setting the From and To Range:

| 3.2.3.2.1.1 | The default date and time will be the first and last data point of the first Data Logger that is read or previewed. If "Read Defined Time Range" is selected after reading the first Data Logger of a group or study, all subsequent Data Loggers will then have matching last data points (eliminating data that is logged while others are being read). |
|-------------|---|
| | are being read). |

- 3.2.3.2.1.2 The "From" and "To" range can be manually set by editing the dates and times in the fields or using the associated buttons.
- 3.2.3.2.1.3 The "From" and "To" range can be set from the graph by zooming in on the desired range, right clicking on the graph and selecting "Set Read Range to Match".

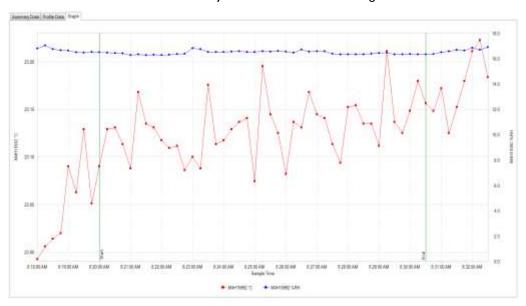


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3.2.3.2.1.4

Once a "From" and "To" range has been selected, "Start" and "End" marker lines will appear on the graph. These lines can be dragged and dropped in order to adjust the From and To range.



3.2.3.2.1.5

Should the logged data contain two (or more) distinct processes, a user can set a time range that focuses on one process, read the Data Loggers, and subsequently change the time range (disable "Read Defined Time Range" and use the "Preview" button again) and read the data for the other process or processes. Two distinct studies will be created (data not included in the defined studies will not be included in the database if "Preview" is used to set the time ranges).

Note:

Once a time range has been set, the batch read mode can be used.



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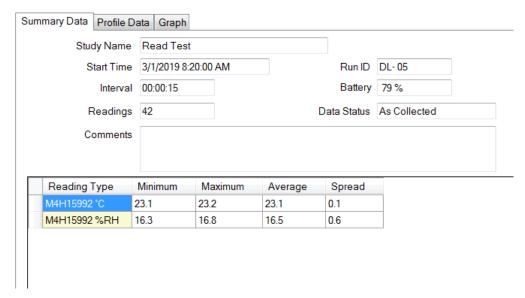
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3.2.4 Data Details

Once a Data Logger is read the data will be displayed in the Read window.

3.2.4.1 Summary Data Tab

Shows programming details and data statistics.



3.2.4.2 Profile Data Tab

The data is listed in a grid with the date and time.

| Summary I | Data Profile Data | Graph | |
|------------|-------------------|----------------|-----------------|
| | Sample Time | M4H15992 °C | M4H15992 %RH |
| ▶ 1 | 3/1/2019 8:20:0 | 23.1 | 16.5 |
| 2 | 3/1/2019 8:20:1 | 23.1 | 16.5 |
| 3 | 3/1/2019 8:20:3 | 23.1 | 16.4 |
| 4 | 3/1/2019 8:20:4 | 23.1 | 16.4 |
| 5 | 3/1/2019 8:21:0 | 23.1 | 16.3 |
| 6 | 3/1/2019 8:21:1 | 23.2 | 16.3 |
| 7 | 3/1/2019 8:21:3 | 23.1 | 16.3 |
| 8 | 3/1/2019 8:21:4 | 23.1 | 16.3 |
| 9 | 3/1/2019 8:22:0 | 23.1 | 16.3 |
| 10 | 3/1/2019 8:22:1 | 23.1 | 16.3 |
| 11 | 3/1/2019 8:22:3 | 23.1 | 16.4 |
| 12 | 3/1/2019 8:22:4 | 23.1 | 16.4 |
| 13 | 3/1/2019 8:23:0 | 23.1 | 16.8 |
| 14 | 3/1/2019 8:23:1 | 23.1 | 16.8 |
| 15 | 3/1/2019 8:23:3 | 23.2 | 16.5 |
| 16 | 3/1/2019 8:23:4 | 23.1 | 16.5 |
| 17 | 3/1/2019 8:24:0 | 23.1 | 16.5 |
| 18 | 3/1/2019 8:24:1 | 23.1 | 16.5 |
| 19 | 3/1/2019 8:24:3 | 23.1 | 16.6 |
| | | | |

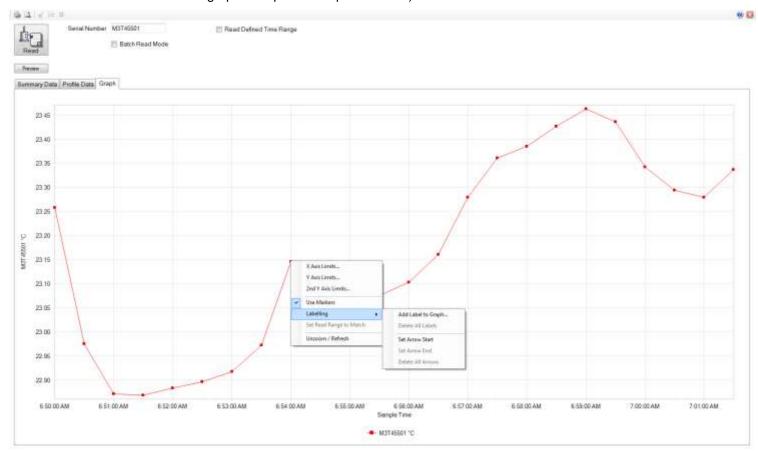


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3.2.4.3 Graph Tab

Graphical display of the data with zooming and axis scale control (right click on graph to expose the options menu).



3.2.4.3.1 Axis Limits

The values that are displayed on the X, Y, and 2nd Y Axes can be set by right clicking on the Graph and selecting X Axis Limits, Y Axis Limits, or 2nd Y Axis Limits.

To change the limits, de-select the Auto Scale Option and enter the limits to be used in the Axis Minimum and Maximum boxes.

The option to display graph lines for each axis can also be selected in Axis Limits option.

3.2.4.3.2 Use Markers

The Graph data can be displayed with or without data markers.

Right click on the Graph and select Use Marker to enable or disable the use of markers. A check mark will be displayed next to Use Markers in the options menu if markers are used.



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3.2.4.3.3 Labelling

Right Clicking on the Graph and selecting Labelling allows the user to insert text or add arrows to the graph.

3.2.4.3.3.1 Add Label to Graph

Selecting the Add Label to Graph option will open a window that the user can use to add additional information at the area that was right clicked on.

After the Label is added to the Graph it can be selected and moved to a different location.

Labels can be removed from the Graph by selecting the Delete All Labels option.

3.2.4.3.3.2 Arrows

Selecting the Set Arrow Start option will set the start area that an arrow will be inserted. The arrow will be added to the Graph after the Set Arrow End option is selected.

After the Arrow is added to the Graph it can be selected and moved to a different location.

Arrows can be removed from the Graph by selecting the Delete All Arrows option.

3.2.4.3.4 Set Data Range to Match

While zoomed in on a section of the Graph and selecting Set Data Range to Match will exclude all other data.

3.2.4.3.5 Unzoom/Refresh

Selecting an area of the Graph will zoom to that area. While zoomed, scrolling sliders for each axis will be available. Right clicking on the zoomed Graph and selecting Unzoom/Refresh will return the Graph display to the original view.

Notes:

 The Graph can be printed or previewed using the Current View print icons located in the upper left corner.



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3.2.4.4 Data Analysis

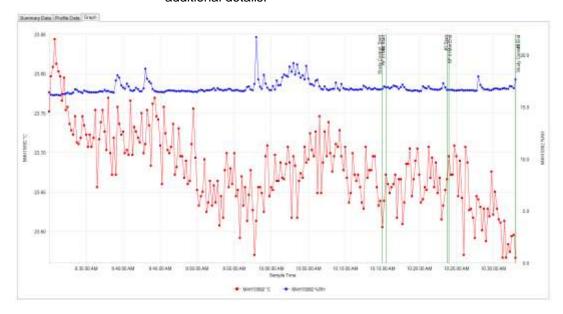
3.2.4.4.1 Data from any of the views can either be printed or copied and pasted into another application using the top menu bar icons.



Data can also be selected by pressing the top left cell in the Profile Data Tab, copied using Ctrl + C, and pasted into another application using Ctrl + V.

| Summary | Data | Profile Data | Graph | | | |
|------------|--------|--------------|----------------|-----------------|--|--|
| Sar Tim | | | M4H15992 °C | M4H15992 %RH | | |
| 1 | 3/1/20 | 19 9:30:0 | 23.8 | 16.4 | | |
| 2 | 3/1/20 | 19 9:30:1 | 23.8 | 16.2 | | |
| 3 | 3/1/20 | 19 9:30:3 | 23.8 | 16.1 | | |
| 4 | 3/1/20 | 19 9:30:4 | 23.8 | 16.1 | | |
| 5 | 3/1/20 | 19 9:31:0 | 23.8 | 16.2 | | |

3.2.4.4.2 If there is a defined study for the data set already created (using Study Start / Stop control of RF Data Loggers), the study range (or ranges if there are multiple studies) will be indicated by vertical study line markers on the Graph Tab. Refer to Section 4.5 for additional details.

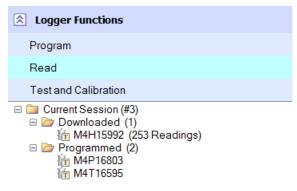




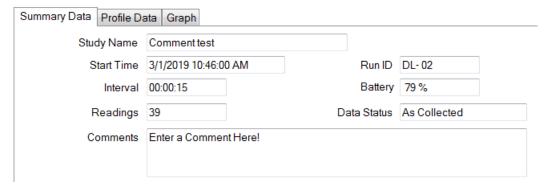
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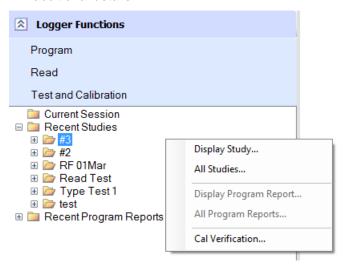
3.2.4.4.3 The Current Session folder will show which Data Loggers have been read, and which have not.



3.2.4.4.4 If a Comment was entered when the Data Logger was programmed, it will be displayed in the Summary Data Tab. The comment can be edited, or a new one added if desired.



3.2.4.4.5 When all Data Loggers have been read, a report for the entire batch or study can be instantly accessed by right clicking on the Study in the Current Session or Recent Studies and selecting the Display Study or All Studies options. Refer to Section 5.0 for additional details.





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3.2.5 Data Logger Reset and Data Recovery

Data Loggers can occasionally reset and stops logging data during operation. A "Reset" can occur due to a low battery, static electricity discharge or excessive mechanical shock. In some cases it is possible to recover the data that had been logged up until the time the reset occurred.

In all cases of data recovery, the data is tagged within the audit trail portion of the database to indicate the issue.

3.2.5.1 MPRF Data Loggers

If recoverable data exists, it is recovered automatically after notification of the Reset event.

3.2.5.2 MPIII Data Loggers

Data is recovered only if the user desires to do so; furthermore, the user must specify the data end point (when valid data stops).

Notes:

 MPRF Data Loggers can also undergo a radio reset caused by insufficient battery power to operate the radio.

When this type of reset occurs, RF transmissions cease but data logging continues.

When the data is downloaded, a notification message is generated.

A radio reset most commonly occurs when using Data Loggers with the radio enabled in ultra-cold environments.



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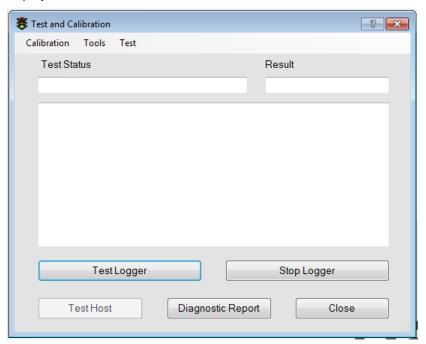
3.3 Test and Calibration

The Test and Calibration option allows the user to perform various tests on a Data Logger, PC Interface, or Repeater.

Note:

RF Communications are not able to be tested using this function.

Select Test and Calibration from the Logger Functions menu. The Test and Calibration window will be displayed.





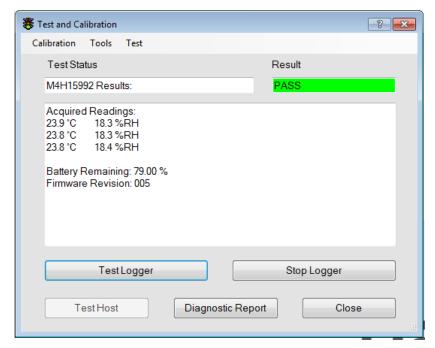
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3.3.1 Test Logger

- 3.3.1.1 Place the Data Logger in the PC Interface.
- 3.3.1.2 Click the "Test Logger" button.
- 3.3.1.3 Test results will be displayed within 12 to 15 seconds. If the Test was successful, logged data will be shown. Data accuracy is not evaluated; the user should verify it seems reasonable. Battery status and firmware revision level will also be displayed.

Report for the Logger Tests can be created if needed, refer to Section 5.1.3.1 for additional details.



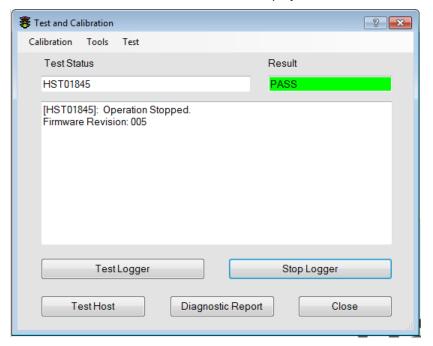
- 3.3.1.3.1 Battery status (% remaining) is an estimate and is based on the date the battery was installed, the number of measurements made, and how many communication events have occurred.
- 3.3.1.3.2 The Battery status can be inaccurate is the Data Logger has been used at extreme temperatures (high or low) or was used with a short interval < 10 to 15 seconds.
- 3.3.1.4 Data Logger test results and battery changes are recorded in the system's audit trail.
- 3.3.1.5 If the Data Logger firmware version needs to be updated, it will be displayed. The firmware upgrade utility is accessed from the Tools menu.
- 3.3.1.6 If the Data Logger is unable to communicate with the PC Interface the Result will be displayed as Fail.



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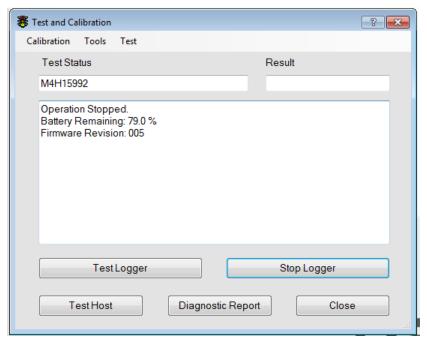
- 3.3.2 Test Host
 - 3.3.2.1 Applies to MPRF PC Interfaces only.
 - 3.3.2.2 Click the "Test Host" button to verify proper USB communications. Test result and firmware revision level will be displayed.



3.3.2.3 Test Host will not be enabled if RF data acquisition is in progress.

3.3.3 Stop Data Loggers

3.3.3.1 Stops data logging and RF transmission. Data can be downloaded at a later time. Firmware revision and battery status will be displayed.





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This is normally used for RF Data Loggers after all the desired data has already been received via RF. It can also be used to stop programmable repeaters.

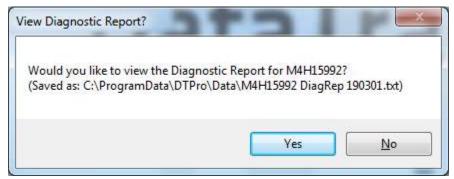
3.3.3.2 When testing or stopping Data Loggers after the battery has been changed or the Data Logger has reset, a message will inquire if a new battery was installed will be generated. Refer to Section 3.3.6.1 for additional details.



3.3.4 Diagnostic Report

3.3.4.1 The Diagnostic Report file contains various Data Logger configuration parameters and can be useful in diagnosing Data Logger problems.

After selecting the Diagnostic Report option a window will be opened asking if the user would like to view the Diagnostic Report . The Diagnostic Report is opened in Notepad and can be saved if required.

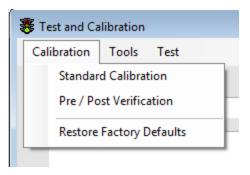




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3.3.5 Calibration Menu



3.3.5.1 Standard Calibration

A 1 or 2 point calibration check or adjustment utility for a Data Logger can be completed using the Standard Calibration option.

Refer to Section 6.2 for additional details.

3.3.5.2 Pre/Post Verification

A multiple point user defined profile calibration check or adjustment utility for a Data Logger can be completed using the Standard Calibration option.

This utility can connect the software with various reference and control equipment and perform completely automated calibration verification.

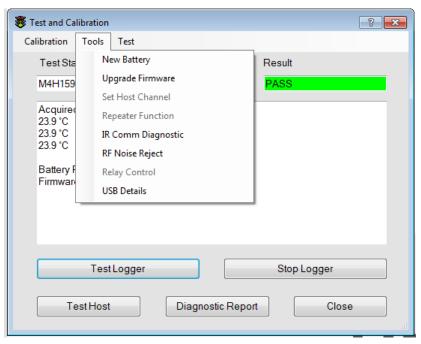
Refer to Section 0 for additional details.

3.3.5.3 Restore Factory Defaults

If an adjustment has been made to a Data Logger calibration, the factory calibration can be restored by selecting the Restore Factory Defaults option.

Refer to Section 6.1 for additional details.

3.3.6 Tools Menu





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3.3.6.1 New Battery

The New Battery option will reset the Data Logger battery percentage after the Data Logger battery has been replaced.

The battery percentage can also be reset if a Data Logger battery is changed and the Data Logger is then tested using the Test Logger option.

3.3.6.1.1 The Battery Change Inquiry window will be displayed. Select Yes to reset the battery percentage, # of measurements, and # of communication events. Selecting No will end the battery reset process.



- 3.3.6.1.2 For MPIII Data Loggers, after Yes is selected the Data Logger will be tested and the Battery Remaining will be reset to 100%.
- 3.3.6.1.3 For MPRF Data Loggers, after Yes is selected the Data Logger and battery must be Depassivated. Allow a few minutes for the Depassivation procedure to complete.

After the Depassivation procedure is completed, test the Data Logger as described in Section 0 to complete the battery reset procedure.

3.3.6.1.4 MPRF Data Loggers can be used with 2 battery types, Standard and Low.

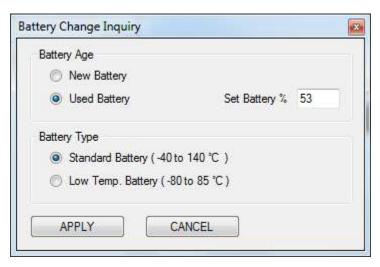
While both batteries can be used below -40°C, Low batteries should be used in applications to help prevent erroneous data recording or premature cessation of data acquisition that has been when standard batteries are used at temperatures below -40°C.

Selecting the Advanced option on the Battery Change Inquiry window allows the user to select the battery type and battery age.



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3.3.6.1.4.1 Battery Age

If it is desired to remove a battery from a Data Logger with the intention of reusing it at a later time (e.g. replacing a Standard battery with the Low battery or removing a battery for long term storage), prior to removing the battery, use the Test Logger option to record the current battery level (e.g. on a log form or directly on the battery using an permanent marker) and then stop the Data Logger using the Stop Logger option.

Remove the battery and store it along with the recorded value When reusing the battery, install it in the Data Logger, and access the Advanced battery options. Set the battery type to either Standard or Low, select the Used Battery option, enter the previously recorded battery gauge value for the battery and click Apply.

Notes:

- Warning: Do not expose low temperature batteries to temperatures greater than 85° C (185° F). Failure to observe temperature limits can result in erroneous data, a ruptured battery, a damaged Data Logger, and/or personal exposure to toxic chemicals with associated health hazards.
- Always dispose of lithium batteries in accordance with local regulations.
- Battery Management is only applicable to MPRF Data Loggers with firmware revision "002" or newer.



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3.3.6.2 Upgrade Firmware

This option allows the firmware of an MPRF Data Logger to be upgraded.

A valid firmware file (typically, a *.HEX file) is required in order to perform an upgrade. A copy of the most recent firmware is included on the installation CD, or the DT Pro Installer package.

A more recent file might be available for download from the Mesa Labs web site (www.mesalabs.com); alternatively, please contact DataTrace Technical Support for assistance in obtaining the most recent firmware file.

| 3.3.6.2.1 | Data Log | ger Firmware Upgrade Procedure |
|-----------|----------|---|
| 3.3.6.2. | 1.1 | Start DT Pro |
| 3.3.6.2. | 1.2 | Put the Data Logger in the PC Interface, access the Logger Test window and Click the Stop Logger button. |
| 3.3.6.2. | 1.3 | Verify proper communications occurred and the serial number of the Data Logger is indicated. |
| 3.3.6.2. | 1.4 | Access the Tools menu and click on the Upgrade Firmware Item. |
| 3.3.6.2. | 1.5 | When prompted, select the firmware upgrade file. A typical file name would be "MPRF Logger-Host REV 002.HEX". It will be located either on the DT Pro installation CD, or in the folder location where it was previously saved (e.g. after a download), or in the DT Pro Upgrade folder (i.e. C:\Program Files\DataTrace Pro\Upgrades). |
| 3.3.6.2. | 1.6 | Wait for DT Pro to load the new firmware into the Data Logger. |
| 3.3.6.2. | 1.7 | When the upgrade is finished, test the Data Logger to |

3.3.6.2.2 Interface Firmware Upgrade Procedure

Note

PC Interfaces do not have firmware and do not require firmware upgrades.

confirm the new revision.

| 3.3.6.2.2.1 | Start DT Pro |
|-------------|---|
| 3.3.6.2.2.2 | Access the Logger Test window and Click the Test Host button. |
| 3.3.6.2.2.3 | Verify proper communications occurred and the serial number of the MPRF PC Interface is indicated. |
| 3.3.6.2.2.4 | Access the Tools menu and click on the Upgrade Firmware Item. |
| 3.3.6.2.2.5 | When prompted, select the firmware upgrade file. A typical file name would be "MPRF Logger-Host REV 002.HEX". It will be located either on the DT Pro installation CD, in the folder location where it was previously saved (e.g. after a download), or in the DT Pro Upgrade folder (i.e. C:\Program Files\DataTrace |

Pro\Upgrades).



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3.3.6.2.2.6 Wait for DT Pro to load the new firmware into the MPRF

PC Interface.

3.3.6.2.2.7 When finished, it is advisable to "Test Host" and confirm

the new revision.

3.3.6.2.3 Known Issues

There have been a few instances of problems arising whereby the new firmware is not loaded, indicated by a verification failure message. Should this occur, it is recommended to test the Data Logger again to verify the actual firmware version, and if needed, try upgrading again prior to returning the Data Logger for service or upgrade at the factory.

In very rare circumstances, the Data Logger's ability to communicate can be compromised by the firmware upgrade process. Should this occur, it can usually be corrected by removing the battery from the Data Logger for 10 or more seconds, and then testing the Data Logger. If this does not resolve the problem, the Data Logger will require factory service.

3.3.6.3 Set Host Channel

The channel of the MPRF PC Interface can be manually set using this option.

Select the Test Host option to verify communication with the MPRF PC Interface, and then select Set Host Channel from the Tools menu. A window will open where the channel can be entered. Select OK to set the new Host Channel.

Warning: Changing the host channel can result in data loss from devices transmitting on the original channel. This option is enabled only after a successful Test Host.

3.3.6.4 Repeater Function

Repeaters can be set to Standard (Unlocked) or Dedicated (locked). The Standard setting will transmit data from both Data Loggers and other Repeaters, while the Dedicated setting will only transmit data from Data Loggers.

3.3.6.5 IR Comm Diagnostic

The IR Comm Diagnostic option is used for troubleshooting issues with the DT Pro Hardware and Software. Contact Mesa Laboratories Technical Services for details on using this option.

3.3.6.6 RF Stream

The RF Stream option is used for troubleshooting issues with the DT Pro Hardware and Software. Contact Mesa Laboratories Technical Services for details on using this option.

3.3.6.7 RF Noise Reject

The RF Noise Reject option is used for troubleshooting issues with the DT Pro Hardware and Software. Contact Mesa Laboratories Technical Services for details on using this option.



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3.3.6.8 Relay Control

The Relay Control option is used for troubleshooting issues with the DT Pro Hardware and Software. Contact Mesa Laboratories Technical Services for details on using this option.

3.3.6.9 USB Details

Selecting the USB Details option will display the USB Driver for the PC Interface, and if a USB Driver upgrade is recommended.

3.4 Addition Logger Functions Menu options

3.4.1 Current Session

□ Current Session (Comment test)
 □ Downloaded (2)
 □ M4H15992 (39 Readings)
 □ M4T16595 (247 Readings)
 □ Programmed (0)

3.4.1.1 Downloaded

As the Data Loggers are read, they will be listed in the Downloaded folder. The total number of Data Loggers that have been downloaded (read) will be listed next to the Downloaded folder.

Right clicking on the Study and selecting Display Study will open the Graph Tab for the downloaded Data Loggers.

Right clicking on an individual Data Logger and selecting Display Study will open the Graph Tab for the selected Data Logger.

Right clicking on a Study or Data Logger and Selecting All Studies will open the Data Selection Tab with all of the Recent Studies listed.

3.4.1.2 Programmed

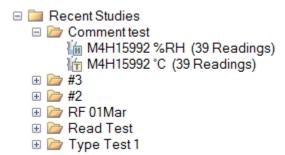
The last Study programmed will be displayed in the Programmed folder of the Current Session folder. The total number of Data Loggers that have been programmed will be listed next to the Programmed folder.

Right Clicking on the Programmed folder or a programmed Data Logger and selecting Display Program Report will display the programming Report for the study which can be printed if needed.

Note:

• If a different menu is opened (i.e. Configuration Tools, Wireless Data, or Reports) the study information will be removed from the Current Session folder.

3.4.2 Recent Studies





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If a different menu is opened (i.e. Configuration Tools, Wireless Data, or Reports) after a Data Logger has been read, the downloaded information will be listed in the Study folder located Recent Studies folder.

Right clicking on the Study and selecting Display Study will open the Graph Tab for the downloaded Data Loggers.

Right clicking on an individual Data Logger and selecting Display Study will open the Graph Tab for the selected Data Logger.

Right clicking on a Study or Data Logger and Selecting All Studies will open the Data Selection Tab with all of the Recent Studies listed.

Refer to Section 5.0 for additional details.

3.4.3 Recent Program Reports

- Recent Program Reports
 - Comment test (2 Loggers)
 - #3 (3 Loggers)
 - #2 (3 Loggers)
 - RF 01Mar (3 Loggers)
 - Read Test (1 Loggers)
 - Type Test 1 (1 Loggers)

A Programming Report can be viewed or printed after all Data Loggers have been programmed.

From the Recent Program Reports folder, right click on the study folder, and select either Display Program Report or All Program Reports.

Selecting All Program Reports will open a window that includes all Program Reports. Pressing the Select button for a Study will open the Programming Report.

3.4.4 Cal Verification

Right clicking on a Data Logger and selecting the Cal Verification option will open the Calibration Verification window. Refer to Section Ofor additional details.

Notes:

The Program Logger Wizard does not allow changing the start time or interval once a MPIII
Data Logger has been programmed. You must reprogram the MPIII Data Logger to change
the interval.

MPRF Data Logger intervals can be changed using Device Configuration if RF Communication was enabled during programming. Refer to Section 2.5.1.4 for additional details.



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4.0 WIRELESS DATA

Once a MPRF Data Logger has been successfully programmed, the Data Logger starts transmitting data, even before start time has elapsed. The Data Logger will only start logging the data once the programmed start time begins.

- 4.1 Database Integrity Control
 - 4.1.1 DT Pro will not display or save data, nor allow control of an "unknown" Data Logger. When a Data Logger is programmed, read, or tested the Data Logger is "known" by the software.
 - In general, RF Data Loggers must be programmed on the computer where RF data will be received. If RF data will be received on a different computer than the Data Loggers were programmed, both computers must be configured with the same RF Domain Name. Refer to Section 2.1.1.2 for additional details.
 - 4.1.2 RF Data Loggers will normally begin transmitting data two or three intervals after they are programmed. Data transmitted prior to the defined logging start time is not retained in the Data Logger's memory.
 - 4.1.3 Repeaters must have their serial numbers manually added, refer to Section 2.5.6 for additional details.
- 4.2 RF Channel Control
 - 4.2.1 In order to receive RF data, both the Data Logger and MPRF PC Interface must use the same channel (frequency). Refer to Sections 2.5.8, 3.1.3, and 3.3.6.3 for additional details.
 - 4.2.2 Channel identification is semi-automatic for Repeaters if there is an active MPRF PC Interface. Refer to Section 2.5.6.1 for details.
- 4.3 RF Reception Control

Two buttons on the Wireless Data menu control RF reception.

- Start RF Reception
- Stop RF Reception

If viewing RF data from a remote database, these buttons will be disabled.

- 4.4 Viewing RF Data
 - 4.4.1 Auto Reception

Click the button. If Auto-Start Reception is enabled, RF reception will automatically start when DT Pro is opened. Refer to Section 2.1.1 for additional details.



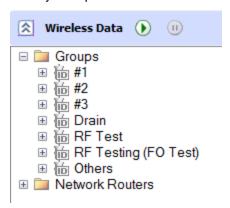
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4.4.2 Sorting

Right clicking on the Wireless Data Menu will allow the user to select how the studies are sorted.

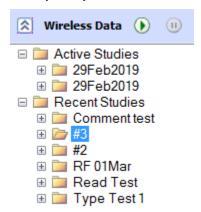
4.4.2.1 Sort by Group



The defined Groups will be listed and the data for the entire Group or individual Data Loggers can be displayed by clicking on the Group name or individual Data Logger.

Clicking on the Group Folder will display a list of all the created Groups and includes the information for the Group Name, Data Logger Measurement types included in the Group, Number of Data Loggers in the Group, the Maximum, Minimum, Average and Spread of the readings of the Group, Associated Study Names, and Alarm Status of the Data Loggers in the Group.

4.4.2.2 Sort by Study



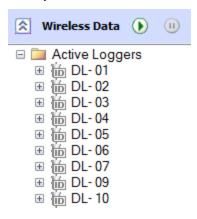
The Active or Recent Studies will be listed and the data for all Data Loggers in the Study or an individual Data Loggers can be displayed by clicking on the Study name or individual Data Logger.



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4.4.2.3 Sort by Run ID



All Data Loggers that were assigned a Run IDs during programming will be listed. The data for each Run ID or an individual Data Logger can be displayed by clicking on the Run ID or individual Data Logger.

4.4.2.4 Sort by RF Path



All active Data Loggers communicating with the MPRF PC Interface or a Repeater will be listed. The data for all Data Loggers or an individual Data Logger can be displayed by clicking on the MPRF PC Interface or Repeater Name or individual Data Logger.

Note:

 MPIII Data Loggers will be displayed in the in the Wireless Data menu, but these Data Loggers do not transmit real-time data.



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4.4.3 Data Display

Click on the Data to be displayed, the selected data will be shown on the right side of the screen.

There are 4 tabs that include different information for the selected data.

Note:

• The displayed data can be changed using the Data Range drop down menu at the top of the Real Time View window.

4.4.3.1 Detail Tab

| | Serial Number | Location / Tag | RuntO | Time Stamp | Value | | Comm | Elapsed | | Signal | Start Time | interval | Read No. | Battery | << |
|-----|---------------|----------------|-------|-----------------------|-------|----|------|---------|----|--------|-----------------------|----------|----------|---------|----|
| Tu. | MATHEMATIC | M4T16594-1 | DL-01 | 3/20/2019 10:42:00 AM | 23.2 | 70 | lin | | 17 | THIII | 3/20/2019 10:37:00 AM | 30 | 11 | 51% | |
| B | M4T16595 °C | M4T16595-1 | DL-02 | 3/20/2019 10:42:00 AM | 23.2 | T | Vie | | 16 | THIII | 3/20/2019 10:37:00 AM | 30 | 11 | 50% | |
| lib | M4T16597 C | M4T16597-1 | DL-03 | 3/20/2019 10:42:00 AM | 23.2 | 70 | Kdo | | 15 | THE | 3/20/2019 10:37:00 AM | 30 | 11 | 78% | |

The Detail Tab shows a summary of the most recent information received from the Data Loggers and includes:

4.4.3.1.1 Serial Number, Location, and Tag ID. of the Data Loggers.

If a Data Logger Channel has been disabled, will be displayed next to the serial number column in the Detail Tab.

- 4.4.3.1.2 Run ID assigned to the Data Logger during programming.
- 4.4.3.1.3 Time Stamp of the last received data for the Data Logger
- 4.4.3.1.4 Data value and data type
- 4.4.3.1.5 Alarm Status

Alarms must be setup for this column to be displayed. Refer to Section 2.5.2 for additional details.

| 4.4.3.1.5.1 | Green indicates there are no alarms occurring. |
|-------------|--|
| 4.4.3.1.5.2 | Red indicates there is an active alarm or an alarm that has not been acknowledged. |
| 4.4.3.1.5.3 | Yellow indicates transitional states before an alarm has been activated or has not reset, e.g. a set point excursion where the allowed time has not yet been exceeded, or an acknowledged alarm that is still in beyond a set point. |
| 4.4.3.1.5.4 | Clicking on an individual Data Logger alarm icon will display the details for an active Alarms. |
| 4.4.3.1.5.5 | A comment describing the cause of the alarm or the effect of the alarm can be added by right clicking on the Alarm Detail and selecting the Add Comment option. |
| 4.4.3.1.5.6 | To clear an Alarm, right click on an active alarm to display the alarm control menu and select the Clear |

Alarm option.

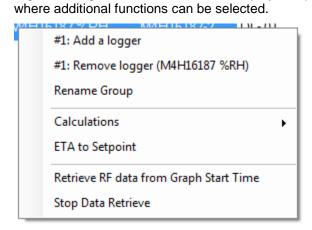


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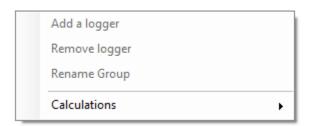
| 4.4.3.1.6 | RF Comn | nunications Status |
|------------|------------------|---|
| 4.4.3.1. | 6.1 | Green indicates normal communications. |
| 4.4.3.1. | 6.2 | Red indicates no data reception for 8 logging intervals. |
| 4.4.3.1. | 6.3 | Yellow indicates marginal communications, i.e. data reception accompanied with the inability of the Data Logger to receive a command, or no data reception for 4 intervals. |
| 4.4.3.1.7 | Elapsed t only). | ime since last communication (shown on the receiving PC |
| 4.4.3.1.8 | RF Signa | l Strength. |
| 4.4.3.1.9 | Additiona | l items (if view is expanded using ">>") |
| 4.4.3.1. | 9.1 | Start Time |
| 4.4.3.1. | 9.2 | Interval |
| 4.4.3.1. | 9.3 | Read no. |
| 4.4.3.1. | 9.4 | Battery % |
| 4.4.3.1.10 | Additiona | I Detail Tab options |

Right Clicking on the Details Tab will display an options menu



Note:

If the System Security Setting is set to Regulatory Compliant only the Add a Logger, Remove a Logger, Rename Group, and Calculations options will be displayed.



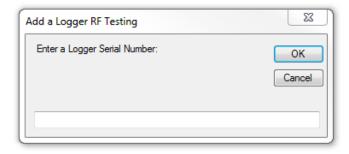


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4.4.3.1.10.1 Add a Logger

If the Wireless Data menu is sorted by Group, Run ID, or RF Path and the Allow Group Assignment in RF View screen option is selected, the user can assign Data Loggers to different groups by selecting the Add a Logger option and then entering the serial number of the Data Logger that will be added to the Group and selecting OK.



Refer to Section 2.1.3 for additional details.

4.4.3.1.10.2 Remove a Logger

If the Wireless Data menu is sorted by Group, Run ID, or RF Path and the Allow Group Assignment in RF View screen option is selected, the user can remove Data Loggers from the Group by selecting the Data Logger, right clicking on the Detail Tab, and then selecting Remove Logger.

4.4.3.1.10.3 Rename Group

If the Wireless Data menu is sorted by Group the user can rename a Group by selecting the Group, right clicking on the Detail view, selecting the Rename Group option, and entering the new Group name.



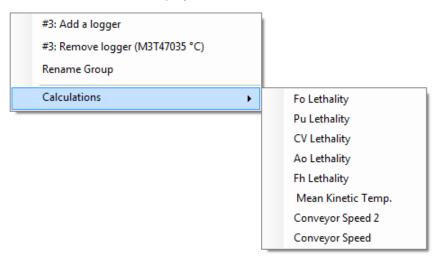


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4.4.3.1.10.4 Calculations

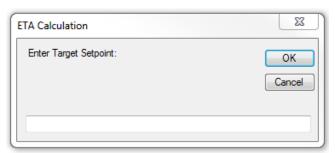
Results for Lethality, Mean Kinetic Temperature or Conveyor Speed calculations can be displayed by selecting Calculations, and then selecting the calculation to display.



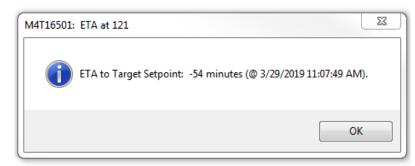
4.4.3.1.10.5 ETA to Setpoint

An estimate of the time required for the Data Logger readings to reach a defined setpoint can be displayed by selecting the ETA to Setpoint option.

When the ETA to Setpoint option is selected a window will open where the Setpoint to use can be entered.



After the Setpoint is entered the estimated time to reach the setpoint will be displayed.





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4.4.3.1.10.6 Retrieve RF data from Graph Start Time

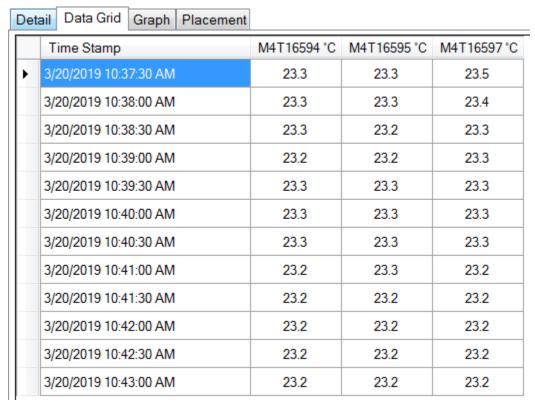
Selecting the Retrieve RF data from Graph Start Time option will force the DT Pro software to attempt to populate any missing data points from the RF Data.

Depending on the RF signal strength not all readings will populate. All data is stored on the Data Logger and will be retrieved when the Data Logger is read. Refer to Section 3.2 for additional details.

4.4.3.1.10.7 Stop Data Retrieve

Selecting the Stop Data Retrieve option will stop the DT Pro from actively populating any missing Data.

4.4.3.2 Data Grid Tab



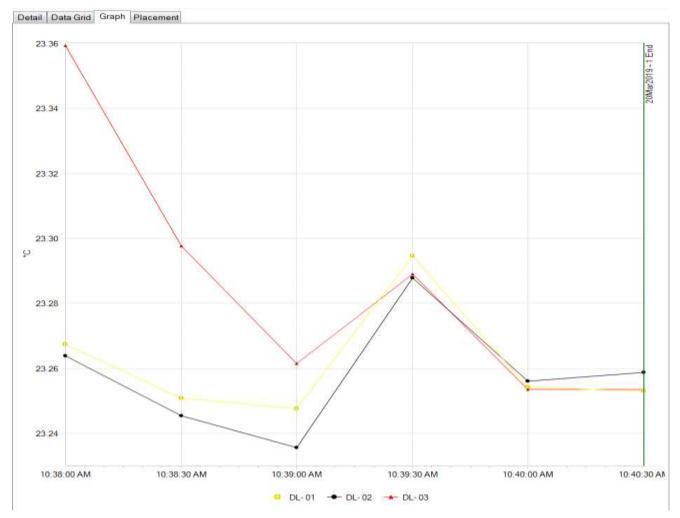
The Data Grid displays the date and time-stamp and readings of the Data Loggers. As data is received the Data Grid is updated.



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4.4.3.3 Graph Tab



The Graph displays the selected data in an XY graphical format with time on the X axis.

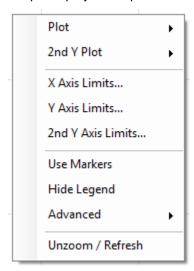
If one or more Data Loggers have defined alarms, these can be displayed automatically on the graph, refer to Section 0 for additional details.



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The Graph can be customized using the options menu. Right clicking on the Graph displays the options menu.



4.4.3.3.1 Plot

Right clicking on the Graph and selecting Plot will display the data type that is displayed. The displayed data will have a check mark next to it. The Data Logger data channels are displayed by default, and calculations must be selected in order to be displayed.

4.4.3.3.2 2nd Y Plot

The data that is displayed on the 2nd Y Axis (right side) can be selected by right clicking on the Graph and selecting 2nd Y Plot. The data displayed on the 2nd Y Axis will have a check mark next to it.

4.4.3.3.3 Axis Limits

The values that are displayed on the X, Y, and 2nd Y Axes can be set by right clicking on the Graph and selecting X Axis Limits, Y Axis Limits, or 2nd Y Axis Limits.

To change the limits, de-select the Auto Scale Option and enter the limits to be used in the Axis Minimum and Maximum boxes.

The option to display graph lines for each axis can also be selected in Axis Limits option.

4.4.3.3.4 Use Markers

The Graph data can be displayed with or without data markers.

Right click on the Graph and select Use Marker to enable or disable the use of markers. A check mark will be displayed next to Use Markers in the options menu if markers are used.



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4.4.3.3.5 Hide Legend

Details about the Graph data is shown in the graph Legend.

Right click on the Graph and select Hide Legend to display or hide the Legend. A check mark will be displayed next to Hide Legend in the options menu if the Legend is hidden.

4.4.3.3.6 Advanced

The Graph can be customized using the Advanced options.

Right click on the Graph and select Advanced to display the customization options.

4.4.3.3.6.1 Line Colors

Selecting the Line Colors option will open a window with a list of all of the data that is currently displayed on the Graph. Selecting an item will open a window that allows the user to change the color for the selected data line.

Line colors are associated with Data Logger serial numbers; the same color will be used for each Data Logger until changed regardless of the selected report.

4.4.3.3.6.2 Set Graph Title

Selecting the Set Graph Title will open a window where the user can enter the title that will be included in on the Graph when printed.

The Graph Title can be removed by selecting Set Graph Title again and deleting the entered title.

4.4.3.3.6.3 Legend Text

The information that is displayed in the Legend can be set to either Serial Number, Location/Tag, or Run ID.

4.4.3.3.7 Unzoom/Refresh

Selecting an area of the Graph will zoom to that area. While zoomed, scrolling sliders for each axis will be available. Right clicking on the zoomed Graph and selecting Unzoom/Refresh will return the Graph display to the original view.

Notes:

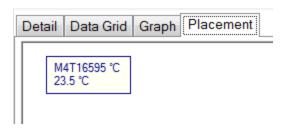
 The Graph can be printed or previewed using the Current View print icons located in the upper left corner.



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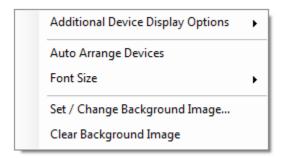
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4.4.3.4 Placement Tab



The Placement view allows the user to display information for the selected Data Loggers and allows an image to be imported and the Data Loggers arranged in specific locations relative to the image. Each Data Logger is represented by a text box. The box can be moved by left clicking on the box and dragging it to the desired location.

The Placement view can be customized using the options menu. Right Clicking on the Placement window displays the options menu.



4.4.3.4.1 Additional Device Display Options

The information displayed for each Data Loggers can be selected using this option. The Start Time, Interval, and Run ID can be displayed.

Selecting the Hide ID option will remove the Data Logger Serial Number and/or Run ID from the Placement view.

4.4.3.4.2 Auto Arrange Devices

The Auto Arrange Device option will move the Data Logger boxes to the left side of the screen form where they can be moved to the desired locations.

4.4.3.4.3 Font Size

The font size of the text box can be changed using the Font Size option.

4.4.3.4.4 Background Images

A background image can be added to the Placement view by selecting the Set / Change Background Image option. The support image types are .bmp, .jpg, and .gif.

The background image can be removed by selecting the Clear Background Image option.



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Notes:

• For more advanced data processing, e.g. viewing lethality calculations for the received data, access the data using the Reports Menu. Refer to Sections 5.1.3 and 5.2.5.4 for additional details.

RF data is still received and saved while accessing the Reports menu.

4.5 Manual Study Control



The icons which provide Manual Study Control are only visible if:

- The Allow Study Manual Start/Stop Control option is enabled, refer to Section 2.1.3 for additional details.
- The data was selected using the Sort by Study option. Un-named studies will not be available for selection.
- 4.5.1 Ensure that RF data from the study is being received.
- 4.5.2 Pressing will move the study to the Recent Studies folder in the Wireless Data menu. After a study has been stopped is can be accessed form the Reports Menu, refer to Section XX for additional details about Reports.
- 4.5.3 Pressing icon will open a window where the new study name can be entered. The new study will be listed in the Active Studies folder.
- 4.5.4 Selecting a Recent Study from the Recent Studies folder and pressing allows the user to enter a new name for the study. Pressing will start a study using the new name.
- 4.5.5 Starting or stopping a study does not affect data collection. The Data Loggers continue to record data until properly read, refer to Section 3.2 for additional details.
 Starting or stopping a study only sets the study start time, end time and/or Data Loggers used in the study.

Note:

- There are no restrictions on study names or their duplication. To prevent confusion, manually created studies should be uniquely named.
- 4.6 Advanced Study Controls



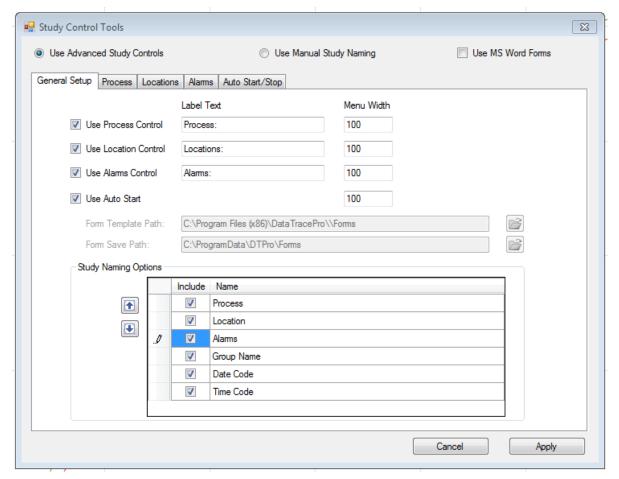
Advanced Study Controls are typically used for Process Monitoring where the same process are repeated and allows for the Studies to be named according to defined settings and for the Studies to be started and stopped by defined parameters.



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Clicking on will open the Study Control Tools window. is only displayed if the Allow Advanced Study Control option is selected. Refer to Section 2.1.3 for additional details.



4.6.1 Use Manual Study Naming

Selecting this option allows for new Studies to be named as needed when they are created, refer to Section 4.5 for additional details.

4.6.2 Use Advanced Study Controls

Selecting this option allows for new Studies to be named by defined by the Study Naming Options.

4.6.2.1 General Setup Tab

4.6.2.1.1 Use Process Control option

Selecting this option will include the Process field in the Study Control Tool bar where the defined Process settings to use for the Study can be selected. The width of the field can be defined using the Menu Width box.



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4.6.2.1.2 Use Location Control

Selecting this option will include the Location field in the Study Control Tool bar where the defined Location settings to use for the Study can be selected. The width of the field can be defined using the Menu Width box.

4.6.2.1.3 Use Alarm Control

Selecting this option will include the Alarm field in the Study Control Tool bar where the defined Alarm settings to use for the Study can be selected. The width of the field can be defined using the Menu Width box.

4.6.2.1.4 Use Auto Start Control

Selecting this option will include the Auto Start field in the Study Control Tool bar where the defined Auto Start and Stop settings to use for the Study can be selected.

4.6.2.1.5 Use MS Work Forms

Selecting the Use MS Word Forms option at the top of the Study Control Tools window will allow the user to select the location of the Form Template and the Save Path.

MS Word Forms can be used as in process reports that will populate with the Study Data, contact Mesa Laboratories Technical Services for additional details on using MS Word Forms.

4.6.2.1.6 Study Naming Options

Test #1 Test #1 Max > 100 Mar-29 13:50

The names of a created studies can be set to include the selected Process, Location, Alarms, Group Name, Date Code, or Time Code.

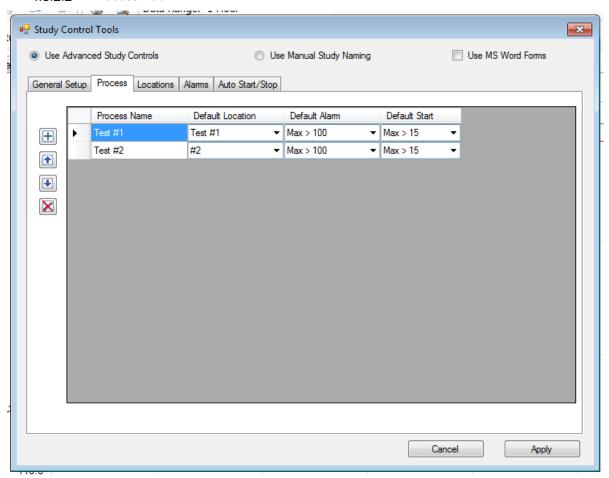
If a Control field was not included in the Study Control Tool bar, it will not be included in the study name.



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4.6.2.2 Process Tab



The Process Tab is used to define the Process Name, Default Location, Default Alarm and Default Start for a Study Process.

Pressing will add a new row where the Process Name can be entered.

The Default Location setting for the Process can be selected from drop down menu listing the defined Location settings, if Location settings have not been defined the drop down menu will not display any information.

The Default Alarm setting for the Process can be selected from drop down menu listing the defined Alarms settings, if Alarm settings have not been defined the drop down menu will not display any information.

The Default Start setting for the Process can be selected from drop down menu listing the defined Auto Start/Stop settings, if Auto Start/Stop setting have not been defined the drop down menu will not display any information.

Pressing or will move the selected Process row up or down and will determine the order the Process is displayed on the Study Control Tool Bar drop down menu.

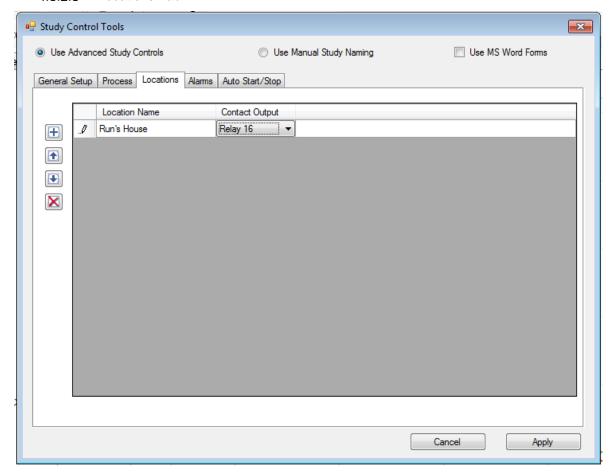
Pressing will delete the selected Process row.



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4.6.2.3 Locations Tab



The Locations Tab is used to define the Location Name and Contact Output for a Study Location.

Pressing will add a new row where the Location Name can be entered.

The Contact Output can be selected from the Contact Output drop down menu. Contact Mesa Laboratories Technical Service for additional details on the Contact Output.

Pressing or will move the selected Location row up or down and will determine the order the Location is displayed on the Study Control Tool Bar drop down menu.

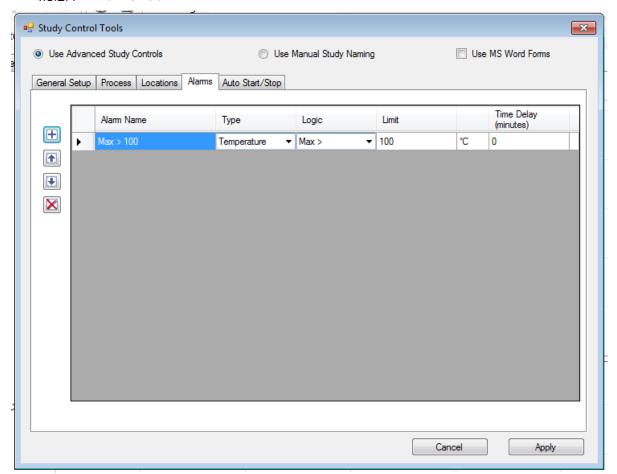
Pressing will delete the selected Location row.



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4.6.2.4 Alarms Tab



The Alarms Tab is used to define the Alarm Name, Type, Logic, Limit, and Time Delay for a Study Alarm.

Pressing will add a new row where the Alarm Name can be entered.

The type of Alarm (i.e. Temperature, Relative Humidity, or Pressure) can be selected from the Type drop down menu.

The Alarm Logic (i.e. Max >, Min >, Max <, Min <, or None) can be selected form the Logic drop down menu.

The Limit for the Alarm can be entered in the Limit column.

The Time Delay before the Alarm is activated can be entered in the Time Delay column.

Pressing or will move the selected Alarm row up or down and will determine the order the Alarm is displayed on the Study Control Tool Bar drop down menu.

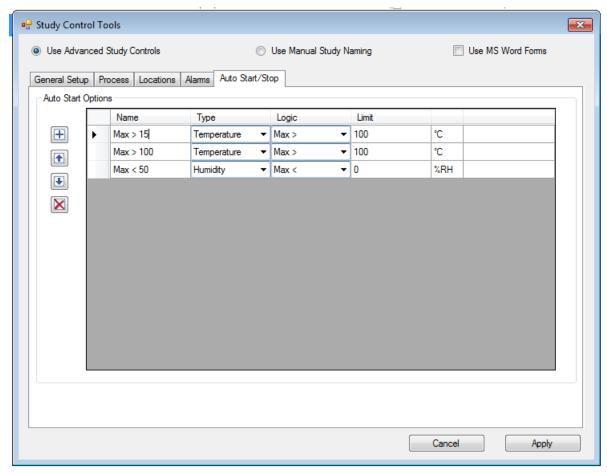
Pressing will delete the selected Alarm row.



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4.6.2.5 Auto Start/Stop Tab



The Auto Start/Stop Tab is used to define the Name, Type, Logic, Limit, and for the Auto Start/Stop settings of a Study.

Pressing will add a new row where the Auto Start/Stop setting Name can be entered.

The type of Auto Start/Stop setting (i.e. Temperature, Relative Humidity, or Pressure) can be selected from the Type drop down menu.

The Auto Start/Stop setting Logic (i.e. Max >, Min >, Max <, Min <, or None) can be selected form the Logic drop down menu.

The Limit for the Alarm can be entered in the Limit column.

Pressing or will move the selected Auto Start/Stop setting row up or down and will determine the order the Auto Start/Stop setting is displayed on the Study Control Tool Bar drop down menu.

Pressing will delete the selected Auto Start/Stop setting row.

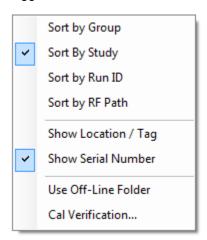


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4.7 Additional Wireless Data Menu Options

Right Clicking on the Wireless Data menu will bring up additional options available for the Data Loggers.



4.7.1 Show Location Tag

The Data Loggers can be displayed in the Wireless Data menu using the Location/Tag assigned to the Data Logger. Refer to Section 2.5.1 for additional details.

4.7.2 Show Serial

The Data Loggers can be displayed in the Wireless Data menu using the Data Logger Serial Number.

4.7.3 Use Offline Folder

When this option is selected, RF Loggers that are not in use (i.e. data is not actively being transmitted) will be placed in the Offline folder.

The Offline folder is displayed when the wireless data is sorted by Group, Run ID, or RF Path.

4.7.4 Cal verification

Right clicking on a Group or individual Data Logger and selecting Cal Verification will open the Calibration Verification window. Refer to Section 0 for additional details.

5.0 REPORTS

DT Pro offers extensive report creation options and offers users great flexibility to customize report templates to fit their needs.

In order to view data and/or create a report the data to be used (e.g. studies have been completed using either the Read Loggers option or Manually stopped in the Wireless Data menu) must be selected. Refer to Sections 3.2 and 4.5 for additional details.

5.1 Selecting Data

5.1.1 Logger Functions Menu

Refer to Sections 3.4.1 and 3.4.2 for details about creating Reports from the Logger Functions Menu.



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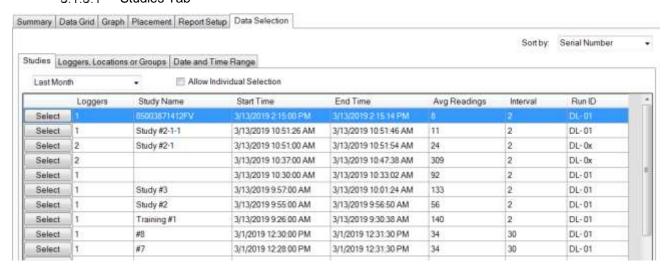
5.1.2 Reports Menu

From the Reports Menu, right click on a Data Logger or study in the Recent Studies folder and select Display Study. If an individual Data Logger is selected the data for only that Data Logger will be displayed.

5.1.3 Historical Data

From the Reports Menu, select the Historical Data option. From the Data Selection Tab there are 2 methods for selecting Historical Data.

5.1.3.1 Studies Tab



5.1.3.1.1 A grid listing the studies will be displayed. The grid lists the study name (if one was defined), the number of Data Loggers (channels) used in the study, the study start and end date/times, average number of readings per Data Logger, data interval, and Run ID.

Clicking on a column title will switch the order the studies are listed in either ascending or descending order.

- 5.1.3.1.2 The time range of the displayed studies can be changed using the drop down menu. The time ranges for the displayed studies can be All Studies (all studies stored in the DT Pro database will be listed), Last Month (all studies completed in the last month will be listed), or Last Week (all studies completed in the last week will be listed).
- 5.1.3.1.3 If the Allow Individual Selection option is chosen, the individual Data Loggers for the studies will be displayed.

Clicking on a column title will switch the order the studies are listed in either ascending or descending order.

5.1.3.1.3.1 The Use Elapsed Time option allows data from different studies (e.g. acquired on different days or in different equipment) to be overlaid in time in order to compare process or other differences. The Time Sliding control (accessed on the Graph Tab) allows the user to manually adjust or "slide" elapsed time data from one Data Logger relative to others so as to align the different data sets and efficiently compare or measure process

differences.



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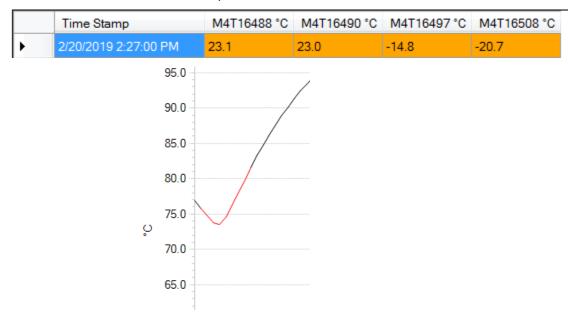
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5.1.3.1.4 There are 2 additional options when selecting Study data.

5.1.3.1.4.1

Include data marked as undesired – includes data that was marked as undesired, refer to Sections 2.1.2, 5.2.2.3, and 5.2.3.4 for additional details.

Undesired data will be colored orange in the Data Grid and Graph.



5.1.3.1.4.2

Include Test Logger Studies – includes data from when Data Loggers were tested, refer to Section 0 for additional details.

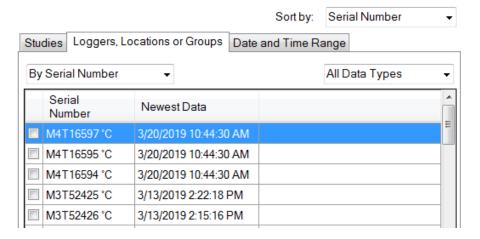
5.1.3.1.5 Click the Select button to display the data for a selected study.

Note:

If a Study name was not assigned when the Data Loggers were programmed, the study will be included in the Studies Tab, but the Study Name will be blank.

5.1.3.2 Selecting Loggers, Locations, or Groups and Date and Time Range Tabs

5.1.3.2.1 Loggers, Locations, or Groups Tab

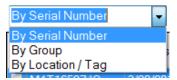




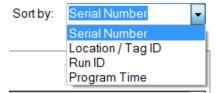
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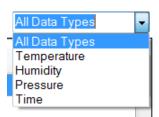
5.1.3.2.1.1 Using the left side drop-down menu, Data Loggers can be displayed by Serial Number, Group, or Location/Tag.



5.1.3.2.1.2 Using the top right drop down menu, Data Loggers can be sorted by Serial Number, Location/Tag ID, Run ID, or Program Time.



5.1.3.2.1.3 Using the right side drop-down menu, Data Loggers can be displayed by measurement type (temperature, relative humidity, pressure, or time). The Default display is set to All Loggers.



5.1.3.2.1.4 Select the Data Logger(s) that will be included in the report.



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5.1.3.2.2 Date and Time Range Tab



5.1.3.2.2.1 Choose the starting time from the available standard ranges (e.g. Last Day, Last Week, All Data, etc.) if desired
5.1.3.2.2.2 If the "To Newest" check box is selected, the data set will end with the most recent available data. If it is not selected, manually set the ending date and time using the calendar (and time display) that will appear.
5.1.3.2.2.3 At the bottom of the window there is an option to include Data that has been marked as Undesired. Refer to Sections 2.1.2, 5.2.2.3, and 5.2.3.4 for additional details.

Once **BOTH** the desired Data Loggers and a Date / Time Range have been selected, click the Get Data button located in the top left corner. The Get Data button will not be displayed unless both the Data Loggers and the Date / Time Range have been selected.

5.1.4 After a Study or Data Logger(s) have been selected, the Graph of the study data will be displayed.



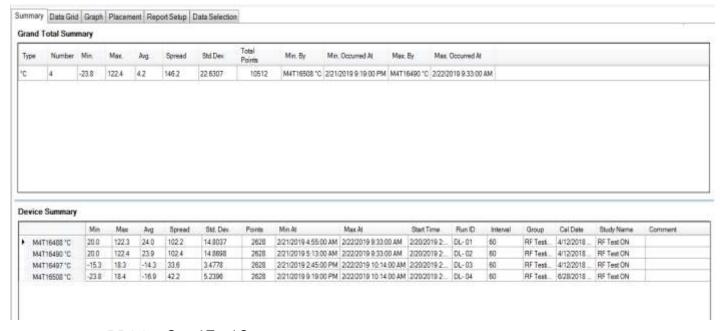
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5.2 Report Creation

Report setup is completed using the different tabs in the Report window.

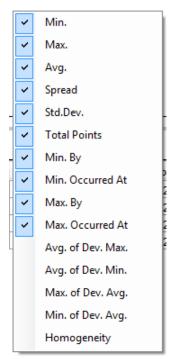
5.2.1 Summary Tab



5.2.1.1 Grand Total Summary

The top grid show the statistical summary for each type of data within the selected data.

Right Clicking on the Summary Tab will display a menu where the items displayed in the Grand Total Summary can be selected.





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The data type and number of Data Loggers included in the selected data are always displayed in the Grand Total Summary.

5.2.1.1.1 Min.

The Minimum Data Logger reading can be selected to be displayed in the Grand Total Summary.

5.2.1.1.2 Max.

The Maximum Data Logger reading can be selected to be displayed in the Grand Total Summary.

5.2.1.1.3 Avg.

The Average value for all of the Data Logger readings can be selected to be displayed in the Grand Total Summary.

5.2.1.1.4 Spread

The difference between the Maximum Data Logger Reading and the Maximum Data Logger Reading can be selected to be displayed in the Grand Total Summary.

5.2.1.1.5 Std. Dev.

The Standard Deviation of the Data Logger readings can be selected to be displayed in the Grand Total Summary.

5.2.1.1.6 Total Points

The total number of data points for all of the selected Data Loggers can be selected to be displayed in the Grand Total Summary.

5.2.1.1.7 Min. By

The Data Logger that had the minimum reading can be selected to be displayed in the Grand Total Summary.

5.2.1.1.8 Min. Occurred At

The Date and Time when the minimum reading occurred can be selected to be displayed.

5.2.1.1.9 Max. By

The Data Logger that had the maximum reading can be selected to be displayed in the Grand Total Summary.

5.2.1.1.10 Max. Occurred At

The Date and Time when the maximum reading occurred can be selected to be displayed in the Grand Total Summary.

5.2.1.1.11 Avg. of Dev. Max.

The Average of the Maximum Readings for all of the selected Data Loggers can be selected to be displayed in the Grand Total Summary.

5.2.1.1.12 Avg. of Dev. Min.

The Average of the Minimum Readings for all of the selected Data Loggers can be selected to be displayed in the Grand Total Summary.



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5.2.1.1.13 Max. of Dev. Avg.

The Maximum Average Data Logger reading can be selected to be displayed in the Grand Total Summary.

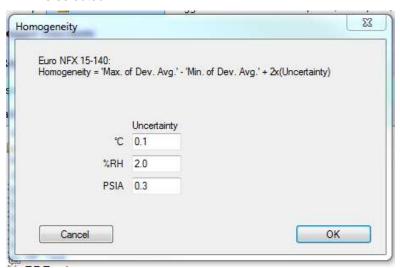
5.2.1.1.14 Min. of Dev. Avg.

The Minimum Average Data Logger reading can be selected to be displayed in the Grand Total Summary.

5.2.1.1.15 Homogeneity

Homogeneity is equal to the Max. of Dev. Avg. minus the Min. of Dev. Avg. plus 2 x (Uncertainty Value) can be selected to be displayed in the Grand Total Summary.

The Uncertainty Value can be set when the Homogeneity option is selected.



Note:

 Max. of Dev. Avg., Min. of Dev. Avg, and Homogeneity are used for calculations required by French Standard FD X 15-140 – May 2013: "Measurement of air moisture - Climatic and thermostatic chambers - Characterization and Verification" (formerly NFX 15-140).

5.2.1.2 Device Summary

The bottom grid show the statistics for the different channels of each Data Logger.

- The Serial Number and Data Type of the selected Data Loggers are always displayed in the Device Summary.
- The Number of Data Points for each selected Data Logger is always displayed in the Device Summary.
- The Start Time for each selected Data Logger is always displayed in the Device Summary if the data was selected as a Study.
- The Run ID for each selected Data Logger is always displayed in the Device Summary if the data was selected as a Study.



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- The Interval for each selected Data Logger is always displayed in the Device Summary if the data was selected as a Study.
- The Group for each selected Data Logger is always displayed in the Device Summary in the Device Summary.
- The Calibration Date for each selected Data Logger is always displayed in the Device Summary if the data was selected as a Study.
- The Study Name for each selected Data Logger is always displayed in the Device Summary if the data was selected as a Study.
- The result of calculations that produce a final value (e.g. Mean Kinetic Temperature or Lethality) will be displayed in the Device Summary. The calculation must be selected to be displayed, refer to Section 5.2.5.4 for additional details.
- 5.2.1.2.1 Min

The Minimum Data Logger reading can be selected to be displayed in the Device Summary.

5.2.1.2.2 Max

The Maximum Data Logger reading can be selected to be displayed in the Device Summary.

5.2.1.2.3 Avg

The Average value for all of the Data Logger readings can be selected to be displayed in the Device Summary.

5.2.1.2.4 Spread

The difference between the Maximum Data Logger Reading and the Maximum Data Logger Reading can be selected to be displayed in the Device Summary.

5.2.1.2.5 Std. Dev.

The Standard Deviation of the Data Logger readings can be selected to be displayed in the Device Summary.

5.2.1.2.6 Min By

The Data Logger that had the minimum reading can be selected to be displayed in the Device Summary.

5.2.1.2.7 Min Occurred At

The Date and Time when the minimum reading occurred can be selected to be displayed in the Device Summary.

5.2.1.2.8 Max By

The Data Logger that had the maximum reading can be selected to be displayed in the Device Summary.

5.2.1.2.9 Max Occurred At

The Date and Time when the maximum reading occurred can be selected to be displayed in the Device Summary.

5.2.1.2.10 Comments



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The comment column in the Device Summary grid shows any comments made when the Data Logger was programmed or read. The comment can be edited (or a new comment added) by clicking on the comment for a Data Logger. Comments are stored in studies for each Data Logger.

If data was not accessed as a study, a new comment will not be saved (a study can be created for the data set using the Graph tools, and a comment subsequently assigned to a Data Logger).

Notes:

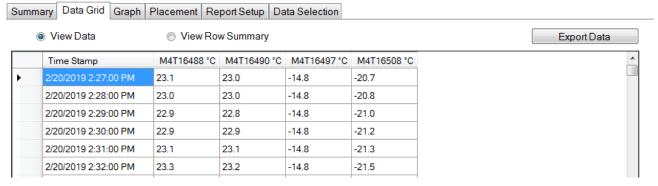
- Comments are not printed as part of the summary printout.
 They can be included in a report as part of the cover page).
- The Summary can be printed or previewed using the Current View print icons located in the upper left corner.
- The summary page can be included in a report refer to Section 5.2.5.2 for additional details.

5.2.2 Data Grid Tab

The Data Grid displays the data time-stamp, values, row summaries and calculations of the selected data, and can be customized as described below. Right clicking on the Data Grid displays the options menu.

5.2.2.1 View Data

Selecting the View Data option will display the data for each data point for all of the selected Data Loggers.



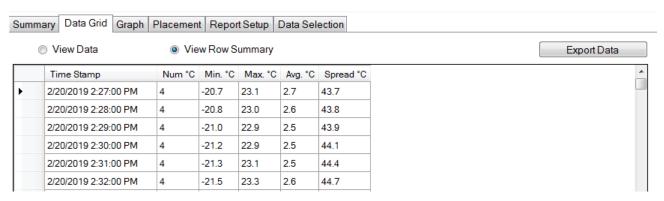
5.2.2.2 View Row Summary

Selecting the View Row Summary option will display the number of Data Loggers, minimum reading, maximum reading, average readings and spread for each data point for all of the selected Data Loggers.



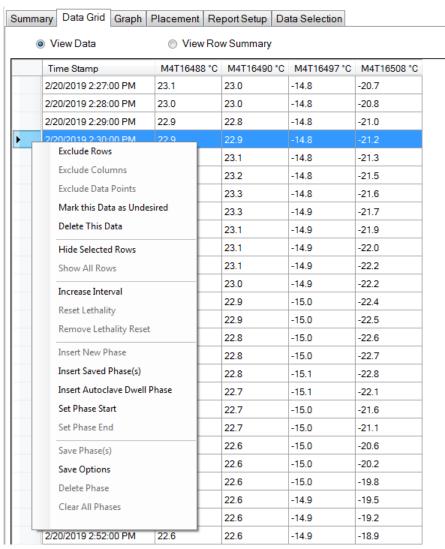
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5.2.2.3 Options Menu

Right Clicking on the Data Grid displays the Options Menu. The Options Menu can be used to perform the functions listed below.



5.2.2.3.1 Data Exclusion by Rows, Columns, or Data Point



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| excluded from data analysis. To exclude column(data, first make sure that the grid view is set on Data, and then highlight the column(s) of data to excluded. Right-click on the highlighted column(s) then select Exclude Columns from the options men 5.2.2.3.1.3 Data Point(s) can be selected and excluded from analysis. To exclude data point(s), first make sure the grid view is set on View Data, and then highligh data point(s) to be excluded. Right-click on highlighted column(s) and then select Exclude | 5.2.2.3.1.1 | Row(s) of data can be selected, and the data excluded from data analysis. To exclude row(s) of data, first make sure that the grid view is set on View Data, and then highlight the row(s) of data to be excluded. Right-click on the highlighted row(s) and then select Exclude Rows from the options menu. |
|--|-------------|---|
| analysis. To exclude data point(s), first make sure the grid view is set on View Data, and then highligh data point(s) to be excluded. Right-click on highlighted column(s) and then select Exclude | 5.2.2.3.1.2 | Column(s) of Data Loggers can be selected and excluded from data analysis. To exclude column(s) of data, first make sure that the grid view is set on View Data, and then highlight the column(s) of data to be excluded. Right-click on the highlighted column(s) and then select Exclude Columns from the options menu. |
| Points from the options menu. | 5.2.2.3.1.3 | Data Point(s) can be selected and excluded from data analysis. To exclude data point(s), first make sure that the grid view is set on View Data, and then highlight the data point(s) to be excluded. Right-click on the highlighted column(s) and then select Exclude Data Points from the options menu. |

Note:

 Excluded data is not deleted; it is not included in the current report data set. In order to recover excluded data, the user must complete the data selection process again.

| 5.2.2.3.2 | Undesire | ed Data |
|------------------|----------|--|
| 5.2.2. | 3.2.1 | Using The "Mark this Data as Undesired" option tags the data so that it will no longer be normally available. |
| 5.2.2. | 3.2.2 | Select the undesired data, right click on the Data Grid, and select Mark this Data as Undesired from the options menu. |
| 5.2.2. | 3.2.3 | The data can still be viewed if the "Include data marked as undesired" option is enabled when selecting data. |
| 5.2.2. | 3.2.4 | Marking Data as Undesired is restricted to Administrators. |
| 5.2.2.3.3 | Data De | letion |
| 5.2.2. | 3.3.1 | Data Deletion permanently deletes the selected rows, columns, or individual cells from the database. |
| 5.2.2. | 3.3.2 | Select the data to be deleted, right click on the Data Grid, |
| | | and select Delete This Data from the options menu. |
| 5.2.2. | 3.3.3 | and select Delete This Data from the options menu. Data deletion is restricted to Administrators. |
| 5.2.2. 5.2.2. | 0.0.0 | · |

Notes:

 Data changes (exclusion, deletion or marking as undesired) are recorded in the audit trail. The audit trail should be included in reports intended to



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comply with 21 CFR Part 11. When used, an option is provided to enter a comment or explanation for the action.

5.2.2.3.4 Hiding Rows

5.2.2.3.4.1 To temporary hide data row(s), select the row(s) to

hide, right-click on the Data Grid and select "Hide

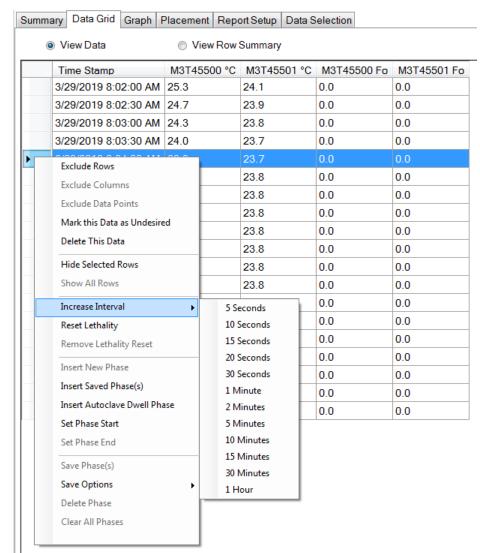
Selected Rows" form the options menu.

5.2.2.3.4.2 Temporarily hidden data can be shown again by right

clicking on the Data Grid and selecting "Show All

Rows" from the options menu.

5.2.2.3.5 Increase Interval



The interval displayed can be increased by selecting the desired time range (rows), right clicking on the selected rows, and selecting Increase Interval from the options menu.

To reset the interval, the user must perform the data selection process again.



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5.2.2.3.6 Reset Lethality

The Lethality Calculation must be selected for this option to be available.

5.2.2.3.6.1

If the lethality calculation needs to be reset to zero (e.g. if the data set contains two or more separate autoclave cycles).

Right click on the data row where the lethality is to be reset and select the reset lethality option. Accumulated Lethality will begin at zero starting at the time of the clicked data point.

5.2.2.3.6.2

The Remove Lethality Reset option disables the Lethality Reset point.

5.2.2.3.7 Phase Control

A phase is a specific time range within the data set upon which a statistical summary, graph, or other data evaluations can be performed. Created phases can be independent of, overlap, or be placed within other phases.

Phase creation using the Data Grid is similar to phase creation using the Graph, refer to Section 5.2.3.5 for additional details.

5.2.2.3.7.1 Insert New Phase

A phase can be defined by selecting rows, right clicking on the rows, and selecting Insert New Phase.

After Insert New Phase is selected a window will be displayed and the user can define the phase name.

5.2.2.3.7.2 Insert Autoclave Dwell Phase

A phase can be inserted to match an Autoclave Dwell Phase in conformance with European Standard NF EN 554 which requires that the start and end of the Dwell Phase occur at equal temperatures/ The Dwell Phase is ended when the temperature readings are lower than the minimum temperature observed during the Phase.

5.2.2.3.7.3 Set Phase Start/End

A phase can be defined by selecting time (row) that the phase started, right clicking on the starting row, selecting Set Phase Start, and then selecting the time (row) that the phase ended, right clicking on the ending row, and selecting Set Phase End.

After Set Phase End is selected a window will be displayed and the user can define the phase name.



Set Phase Start
Set Phase End
Save Phase(s)
Save Options

Delete Phase

Clear All Phases

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Saving Phases 5.2.2.3.7.4 Summary Data Grid Graph Placement Report Setup Data Selection View Data View Row Summary M3T45500 °C M3T45501 °C M3T45500 Fo M3T45501 Fo Time Stamp 3/29/2019 8:02:00 AM 25.3 24.1 0.0 0.0 3/29/2019 8:02:30 AM 24.7 23.9 0.0 0.0 3/29/2019 8:03:00 AM 24.3 23.8 0.0 0.0 3/29/2019 8:03:30 AM 24.0 23.7 0.0 0.0 23.7 **Exclude Rows** 23.8 0.0 0.0 Exclude Columns 23.8 0.0 0.0 **Exclude Data Points** 23.8 0.0 0.0 Mark this Data as Undesired 23.8 0.0 0.0 Delete This Data 0.0 23.8 0.0 23.8 0.0 0.0 Hide Selected Rows 23.8 0.0 0.0 Show All Rows 23.8 0.0 0.0 Increase Interval 23.8 0.0 0.0 Reset Lethality 23.8 0.0 0.0 Remove Lethality Reset 23.7 0.0 0.0 Insert New Phase 23.7 0.0 0.0 Insert Saved Phase(s) 23.7 0.0 0.0 Insert Autoclave Dwell Phase 23.7 0.0 0.0

>

Phases can be saved after they have been defined by right clicking on the data gird and selecting Save Phase(s) form the options menu.

Relative to the start of data (elapsed time) Relative to a Temperature Setpoint

Relative to the maximum temperature

Relative to the minimum temperature

After a phase has been saved, it can then be inserted into a data set.

When a phase is saved, the recorded data consists of the phase name, its duration and the elapsed time of the phase start relative to a reference time.

The reference time is the point where the saved phase will be inserted.

The Save Option defines what the reference time will be.



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5.2.2.3.7.4.1 Relative to the start of data (elapsed time)

The reference time will be the start of the phase data.

For example, if a phase has been set to start 17 minutes after the start of data collection, the saved phase can be inserted into a different data set 17 minutes after the time of the first data point is recorded.

5.2.2.3.7.4.2 Relative to the Temperature Set Point

A temperature set point will be requested, and the reference time will be the first occurrence or transition across this temperature within the data.

For example, if a phase has been declared that starts 3 minutes before the first time a 120°C is observed in the data, and 120°C is declared as the set point, when this saved phase is inserted into a new and different data set, it will also begin 3 minutes prior to the first occurrence of 120°C within the new data set.

Note:

 The set point can be either a high or a low value (e.g. -15), directionality (> or < logic), and is presumed to be relative to the very first data measurement.

5.2.2.3.7.4.3 Relative to the Maximum/Minimum Temperature

Similar to temperature set point, but the reference for elapsed time will be the time at which the maximum or minimum temperature was observed in the data set.

5.2.2.3.7.5 Delete Phase

Individual phases can be deleted using the Delete Phase Option.

rnase Option.

5.2.2.3.7.6 Clear All Phases

All Phases can be deleted using the Clear All Phases option.

Notes:

Phases defined using the Data Grid will also appear on the Graph view.



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5.2.2.3.8 Reference Data Logger(s)

The Temperature Difference, Differential Pressure and/or Saturated Steam Pressure calculation must be selected for this option to be available.

5.2.2.3.8.1

A Reference Data Logger must be selected for the Temperature Difference, Differential Pressure, or Saturated Steam Pressure calculations to be displayed on the Summary Tab, Data Grid Tab, or included on the report.

5.2.2.3.8.2

From the Data Grid, select the column for the Data Logger that will be used as the reference, right click on the column, and scroll to the bottom of the options menu and select the calculation that the Data Logger will be used as a reference for.

Notes:

- A temperature channel must be used for Temperature Difference and Saturated Steam Pressure calculations.
- A pressure channel must be used for Differential Pressure calculations.

5.2.2.3.9 Enabling/Disabling Data Logger Calculations

Individual Data Loggers can be removed from calculations by selecting the Data Logger's column, right clicking on the column, and selecting the Calculations option.

The available calculations for the Data Logger will be displayed. Enabled calculations will have a check mark next to the calculation name.

Notes:

- The Data Grid can be printed or previewed using the Current View print icons located in the upper left corner.
- The Data Grid can be exported as a Text (Tab Delimited) file using the Export Data option in the top right corner. The Data Grid can also be copied by selecting all of the data and pressing Ctrl + C.

Exported or copied data does not fall under the 21 CFR Part 11 requirements and should be done at the user's discretion.

The Data Grid can be included in a report, refer to Section 5.2.5.2 for additional details.

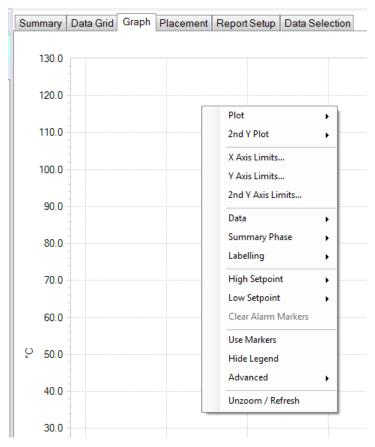


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5.2.3 Graph Tab

The Graph displays the selected data in an XY graphical format with time on the X axis. The Graph can be customized using the options menu. Right clicking on the Graph displays the options menu.



Note:

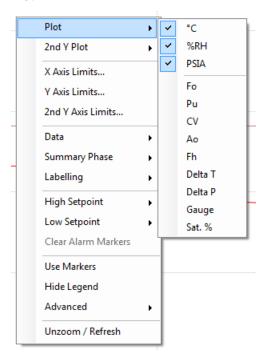
• If one or more Data Loggers have defined alarms, The Alarm Setpoints can be displayed automatically on the graph, refer to Section 0 for additional details.



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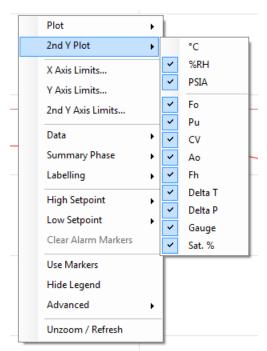
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5.2.3.1 Plot



Right clicking on the Graph and selecting Plot will display the data type that is displayed. The displayed data will have a check mark next to it. The Data Logger data channels are displayed by default, and calculations must be selected in order to be displayed.

5.2.3.2 2nd Y Plot





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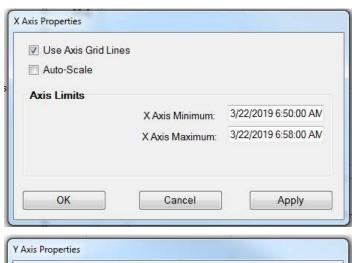
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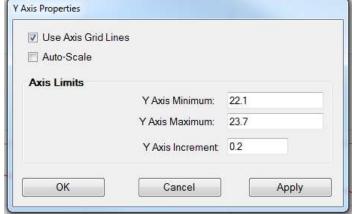
The data that is displayed on the 2^{nd} Y Axis (right side) can be selected by right clicking on the Graph and selecting 2^{nd} Y Plot. The data displayed on the 2^{nd} Y Axis will have a check mark next to it.

5.2.3.3 Axis Limits

The values that are displayed on the X, Y, and 2nd Y Axes can be set by right clicking on the Graph and selecting X Axis Limits, Y Axis Limits, or 2nd Y Axis Limits.

To change the limits, de-select the Auto Scale Option and enter the limits to be used in the Axis Minimum and Maximum boxes.







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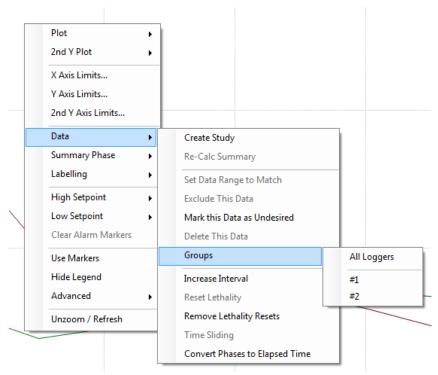


The option to display graph lines for each axis can also be selected in Axis Properties window.

5.2.3.4 Data

The Data options menu allow the user to perform various data management functions. They are generally only applicable to a subset of data arrived at by zooming in on a desired range of data.

Right clicking on the Graph and selecting Data will display the options for phase creation and control.





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5.2.3.4.1 Create Study

Selecting Create Study from the Data menu will open a window where the user can enter a study name for the selected data. This process can be repeated as needed to create sub-sets of the data for later individual processing. The created studies will be listed in the Studies Tab with the entered name and the defined start and end times, refer to Section 5.1.3.1 for additional details.

5.2.3.4.2 Re-Calc Summary

While zoomed in on a section of the Graph and selecting Re-Calc Summary will update the Summary View with the statistics from the zoomed time range.

Note:

 Un-zoom / Refresh the graph to restore the summary calculation for the entire data set.

5.2.3.4.3 Set Data Range to Match

While zoomed in on a section of the Graph and selecting Set Data Range to Match will exclude all other data.

5.2.3.4.4 Exclude This Data

While zoomed in on a section of the Graph and selecting Exclude This Data will exclude the selected data.

5.2.3.4.5 Mark this Data as Undesired

While zoomed in on a section of the Graph and selecting Mark this Data as Undesired will mark the selected data as undesired.

The data can be included in the Report if required. Refer to Sections 5.1.3 for additional details.

Note:

- Marking Data as Undesired is restricted to the Administrator or Power User permission levels.
- Data changes (exclusion, deletion or marking as undesired) are recorded in the audit trail. The audit trail should be included in reports intended to comply with 21 CFR Part 11.

5.2.3.4.6 Delete This Data

While zoomed in on a section of the Graph and selecting Delete This Data will delete the selected data from the DT Pro database.

Note:

- Deleting Data is restricted to the Administrator or Power User permission levels.
- Data deletion using the Graph can be prohibited in the system setup, in which case the menu item will not be available. Refer to Section 2.1.2.3 for additional details.



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 Data changes (exclusion, deletion or marking as undesired) are recorded in the audit trail. The audit trail should be included in reports intended to comply with 21 CFR Part 11.

5.2.3.4.7 Groups

If the Data Loggers being viewed belong to different groups, use the Group option to view only the selected group. Summary information will also be only for the selected group. Select the All Loggers option to return to the standard view.

This option is not visible if the Data Loggers have not been assigned a group or there is only one group present. If desired, a report can be configured to include sub-summaries by group. Refer to Section 0 for details.

5.2.3.4.8 Increase Interval

The interval displayed can be increased by selecting the desired time range (rows), right clicking on the selected rows, and selecting Increase Interval from the options menu.

To reset the interval, the user must perform the data selection process again.

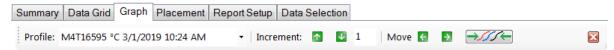
5.2.3.4.9 Reset Lethality

A Lethality Calculation must be selected for this option to be available.

If the lethality calculation needs to be reset to zero (e.g. if the data set contains two or more distinct autoclave cycles). Right click on the data point in the Graph where the lethality is to be reset and select the reset lethality option. Accumulated Lethality will begin at zero starting at the time of the clicked data point.

The Remove Lethality Reset option disables the reset point.

5.2.3.4.10 Time Sliding



The Time Sliding menu item open a tool-bar which allows the user to select a Data Logger from the drop down menu, and move data left or right on the graph (earlier or later in time) relative to the other Data Loggers.

The time sliding tool will be available only when data was selected by Study and by individual Data Logger, with the Use Elapsed Time option checked, refer to Section 5.1.3.1 for additional details.

Time Sliding can be closed by clicking on in the top right corner of the Graph.

Notes:



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- The Create Study option allows distinct data ranges from within a single process or test to be evaluated in an elapsed time manner.
- Create phases within an elapsed time data set in order to accurately quantify process time/duration differences.

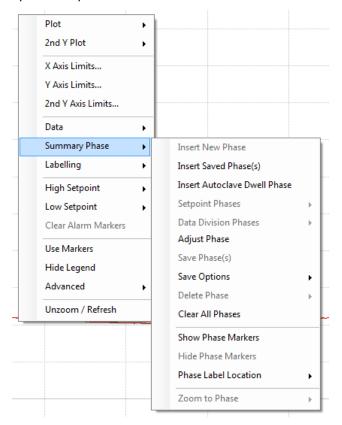
5.2.3.4.11 Convert Phases to Elapsed Time

If a Studies contains multiple processes (e.g. multiple cook / retort cycles) they can be overlain to determine if the processes met the defined criteria by selecting the Convert Phases to Elapsed Time option.

5.2.3.5 Summary Phase

A phase is a specific time range within the data set upon which statistical summary, graphs, or other data evaluations can be performed. Phases can be nested (i.e. a unique phase can be defined without regard to the boundaries of any other phases).

Right clicking on the Graph and selecting Summary Phase will display the options for phase creation and control.



Phase creation using the Graph is similar to phase creation using the Data Grid, refer to Section 5.2.2 for additional details.



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5.2.3.5.1 Insert New Phase

Zoom in on the area where the phase will be inserted and then right click on the Zoomed Graph and select Insert New Phase. A window will open allowing the user to name the phase.

The Phase Adjustment bar is now displayed.

5.2.3.5.1.1 Phase Adjustment Bar

Select either Phase Start or Phase End from the drop down menu on the left side of the bar.

The increment that the Phase Start or End is adjusted can be changed using the up and down arrows. The Move Arrows will move the selected Phase point the entered increment. Phase timing can also be adjusted by dragging and dropping phase lines as desired.

The Duration window displays the current duration of the phase and can be used to accurately quantify the duration of various process events.

The location that the Phase name is displayed can be selected form the Label window.

The Phase Adjustment bar can be closed by clicking on the red X on the right side and opened by selecting the Adjust Phase option from the Summary Phase menu.

5.2.3.5.2 Insert Saved Phase(s)

Previously saved phase can be inserted into a different data set by selecting the Insert Saved Phase(s) option. Refer to Section 5.2.3.5.7 for additional details.

5.2.3.5.3 Insert Autoclave Dwell Phase.

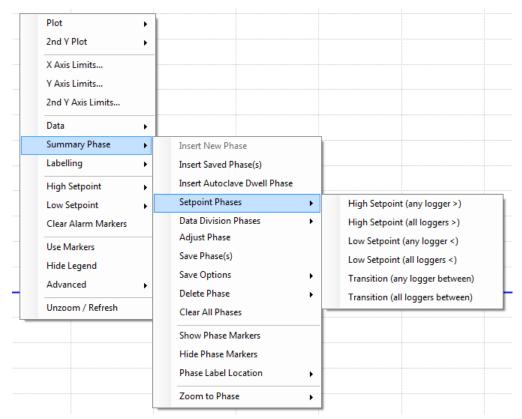
A phase can be inserted to match an Autoclave Dwell Phase in conformance with European Standard NF EN 554 which requires that the start and end of the Dwell Phase occur at equal temperatures/ The Dwell Phase is ended when the temperature readings are lower than the minimum temperature observed during the Phase.



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5.2.3.5.4 Setpoint Phases



Once the high and low setpoints have been defined a phase can be created based on the setpoints. Refer to Section 0 for additional details.

High Setpoint (any logger >) – A phase is created when the reading of any Data Logger reaches or exceeds the high setpoint. The phase ends when all of the Data Logger readings are below the high setpoint.

High Setpoint (all loggers >) – A phase is created when the reading of all of the Data Loggers reach or exceed the high setpoint. The phase ends when one of the Data Logger readings goes below the high setpoint.

Low Setpoint (any logger <) – A phase is created when the reading of any Data Logger reaches or exceeds the Low setpoint. The phase ends when all of the Data Logger readings are below the low setpoint.

Low Setpoint (all loggers <) – A phase is created when the reading of all of the Data Loggers reach or exceed the low setpoint. The phase ends when one of the Data Logger readings goes above the low setpoint.

Transition (any logger between) – A phase is created when any of the Data Logger reading are between the high and low setpoints. The phase ends when all of the Data Logger readings are outside of the setpoints.

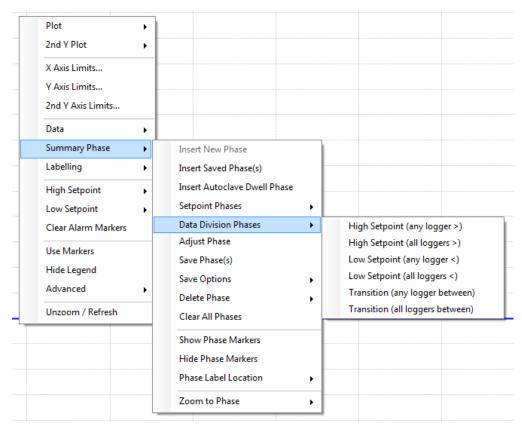


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Transition (all loggers between) – A phase is created when all of the Data Logger readings are between the high and low setpoints. The phase ends when one of the Data Logger readings goes outside of the setpoints.

5.2.3.5.5 Data Division Phases



The data division phase options are intended to split views of data sets that contain multiple processes (e.g. multiple cook/retort cycles) based on the defined setpoints.

Once the high and low setpoints have been defined a phase can be created based on the setpoints.

High Setpoint (any logger >) – A phase is created when the reading of any Data Logger reaches or exceeds the high setpoint. The phase ends when all of the Data Logger readings are below the high setpoint.

High Setpoint (all loggers >) – A phase is created when the reading of all of the Data Loggers reach or exceed the high setpoint. The phase ends when one of the Data Logger readings goes below the high setpoint.

Low Setpoint (any logger <) – A phase is created when the reading of any Data Logger reaches or exceeds the Low setpoint. The phase ends when all of the Data Logger readings are below the low setpoint.



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Low Setpoint (all loggers <) – A phase is created when the reading of all of the Data Loggers reach or exceed the low setpoint. The phase ends when one of the Data Logger readings goes above the low setpoint.

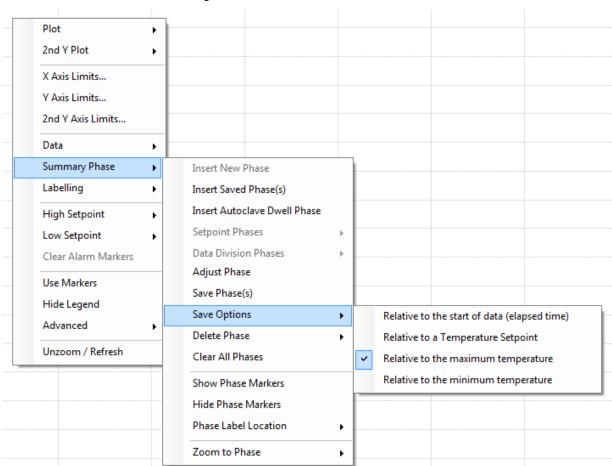
Transition (any logger between) – A phase is created when any of the Data Logger reading are between the high and low setpoints. The phase ends when all of the Data Logger readings are outside of the setpoints.

Transition (all loggers between) – A phase is created when all of the Data Logger readings are between the high and low setpoints. The phase ends when one of the Data Logger readings goes outside of the setpoints.

5.2.3.5.6 Adjust Phase

Selecting the Adjust Phase option will open the Phase Adjustment tool bar, if not already open.

5.2.3.5.7 Saving Phases





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Phases can be saved after they have been defined on the Graph and selecting Save Phase(s) form the options menu.

After a phase has been saved, it can then be inserted into a data set.

When a phase is saved, the recorded data consists of the phase name, its duration and the elapsed time of the phase start relative to a reference time.

The reference time is the point where the saved phase will be inserted.

The Save Option defines what the reference time will be.

5.2.3.5.7.1.1 Relative to the start of data (elapsed time)

The reference time will be the start of the phase data.

For example, if a phase has been set to start 17 minutes after the start of data collection, the saved phase can be inserted into a different data set 17 minutes after the time of the first data point is recorded.

5.2.3.5.7.1.2 Relative to the Temperature Set Point

A temperature set point will be requested, and the reference time will be the first occurrence or transition across this temperature within the data.

For example, if a phase has been declared that starts 3 minutes before the first time a 120°C is observed in the data, and 120°C is declared as the set point, when this saved phase is inserted into a new and different data set, it will also begin 3 minutes prior to the first occurrence of 120°C within the new data set.

Note:

 The set point can be either a high or a low value (e.g. -15), directionality (> or < logic), and is presumed to be relative to the very first data measurement.

5.2.3.5.7.1.3 Relative to the Maximum/Minimum Temperature

Similar to temperature set point, but the reference for elapsed time will be the time at which the maximum or minimum temperature was observed in the data set.

5.2.3.5.8 Delete Phase

Individual phases can be deleted using the Delete Phase Option.



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5.2.3.5.9 Clear All Phases

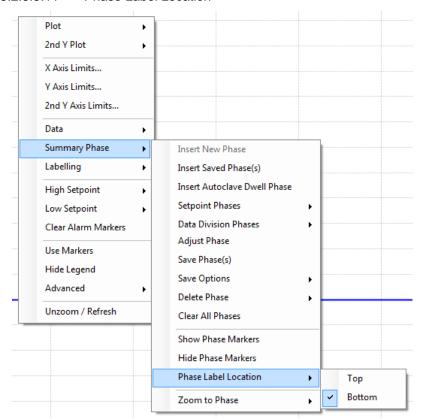
All Phases can be deleted using the Clear All Phases option.

5.2.3.5.10 Phase Markers

By default, the markers for the phase are shown.

Phase markers can be hidden by selecting the Hide Phase Markers option and shown by selecting the Show Phase Makers option.

5.2.3.5.11 Phase Label Location



The location of the Phase Label can be selected from the Summary Phase menu.

Note:

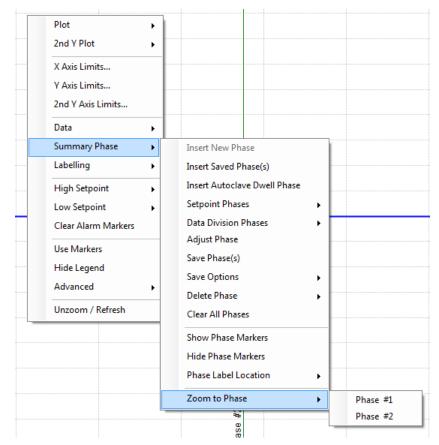
 The Phase Adjustment Bar allows for label location options that are not available from the Phase Label Location menu option.



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5.2.3.5.12 Zoom To Phase



The user can zoom to individual phase by selecting the phase from the desired Phase menu.

Notes:

- Phases defined using the Graph view will also appear on the Data Grid.
- If Phases are created using the Setpoint Phases or Data Division Phases, they will remain active for all data sets until they are removed using the Delete Phase or Clear Alarm Markers option.

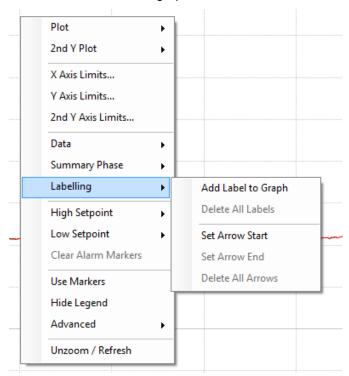


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5.2.3.6 Labelling

Right Clicking on the Graph and selecting Labelling allows the user to insert text or add arrows to the graph.



5.2.3.6.1 Add Label to Graph

Selecting the Add Label to Graph option will open a window that the user can use to add additional information at the area that was right clicked on.

After the Label is added to the Graph it can be selected and moved to a different location.

Labels can be removed from the Graph by selecting the Delete All Labels option.

5.2.3.6.2 Arrows

Selecting the Set Arrow Start option will set the start area that an arrow will be inserted. The arrow will be added to the Graph after the Set Arrow End option is selected.

After the Arrow is added to the Graph it can be selected and moved to a different location.

Arrows can be removed from the Graph by selecting the Delete All Arrows option.



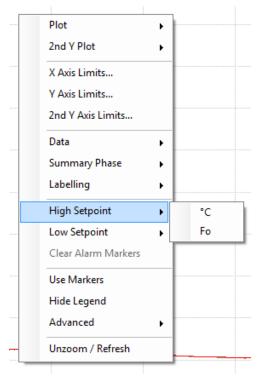
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5.2.3.7 Setpoints

High and Low setpoints can be added to the graph to help show if the data was above, below or within the setpoint.

Right clicking on the Graph and selecting either the High or Low Setpoint option will display a list of the available data types shown on the Graph. Selecting a data type will open a window where the setpoint can be entered.



After a Setpoint is added to the Graph it can be selected and moved to a different location.

Setpoints can be removed from the Graph by selecting the Clear Alarm Markers option.

5.2.3.8 Use Markers

The Graph data can be displayed with or without data markers.

Right click on the Graph and select Use Marker to enable or disable the use of markers. A check mark will be displayed next to Use Markers in the options menu if markers are being used.

5.2.3.9 Hide Legend

The Serial Number or Tag ID of the Graph data can be shown in the Graph Legend.

Right click on the Graph and select Hide Legend to display or hide the Legend. A check mark will be displayed next to Hide Legend in the options menu if the Legend is hidden.



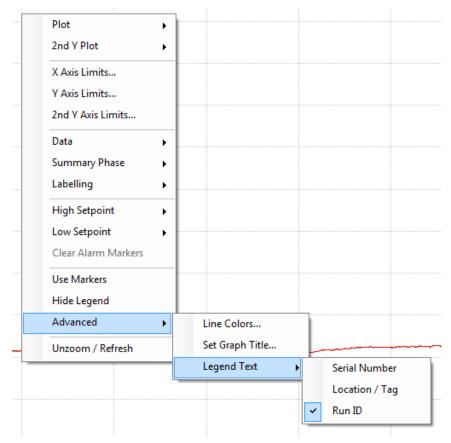
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5.2.3.10 Advanced

The Graph can be customized using the Advanced options.

Right click on the Graph and select Advanced to display the customization options.



5.2.3.10.1 Line Colors

Selecting the Line Colors option will open a window with a list of all of the data that is currently displayed on the Graph. Selecting an item will open a window that allows the user to change the color for the selected data line.

Line colors are associated with Data Logger serial numbers; the same color will be used for each Data Logger until changed regardless of the selected report.

5.2.3.10.2 Set Graph Title

Selecting the Set Graph Title will open a window where the user can enter the title that will be included in on the Graph when printed or included in a Report.

The Graph Title can be edited or removed by selecting Set Graph Title again and changing or deleting the entered title.

5.2.3.10.3 Legend Text

The information that is displayed in the Legend can be set to either Serial Number, Location/Tag, or Run ID.



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5.2.3.11 Unzoom/Refresh

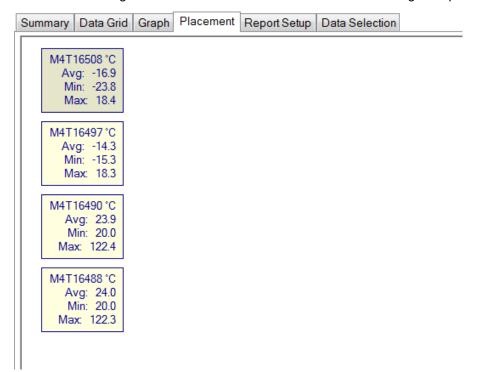
Selecting an area of the Graph will zoom to that area. While zoomed, scrolling sliders for each axis will be available. Right clicking on the zoomed Graph and selecting Unzoom/Refresh will return the Graph display to the original view.

Notes:

- The Graph can be printed or previewed using the Current View print icons located in the upper left corner.
- The Graph can be included in a report, refer to Section 5.2.5.2 for additional details.

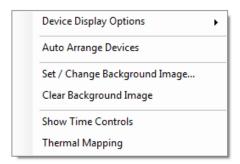
5.2.4 Placement Tab

The Placement view allows the user to display information for the selected Data Loggers and allows an image to be imported and the Data Loggers arranged in specific locations relative to the image. The Placement view can be customized using the options menu.



Each Data Logger is represented by a text box. The box can be moved by left clicking on the box and dragging it to the desired location.

Right Clicking on the Placement window displays the options menu.

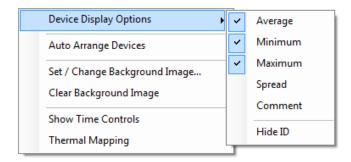




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5.2.4.1 Device Display Options



The information displayed for each Data Loggers can be selected using this option. The average reading, minimum reading, maximum reading, spread (difference between min and max readings) and the Data Logger comment can be selected to be displayed.

If the Time Control bar is open, the Last Value information can also be displayed for each Data Logger.

The user can hide the Data Logger ID by selecting the Hide ID option.

5.2.4.2 Auto Arrange Devices

The Auto Arrange Device option will move the Data Logger boxes to the left side of the screen where they can then be moved to the desired locations.

5.2.4.3 Background Images

A background image can be added to the Placement view by selecting the Set / Change Background Image option. The support image types are .bmp, .jpg, and .gif.

The background image can be removed by selecting the Clear Background Image option.

The background image is associated with the selected report template and will automatically appear when the report is selected.

5.2.4.4 Show Time Controls

Selecting Show Time Controls will open the Time Controls bar at the bottom of the Placement window.

If the Show Time Controls is selected before selecting Thermal Mapping the Min, Max, Avg. and Spread information will not be populated.

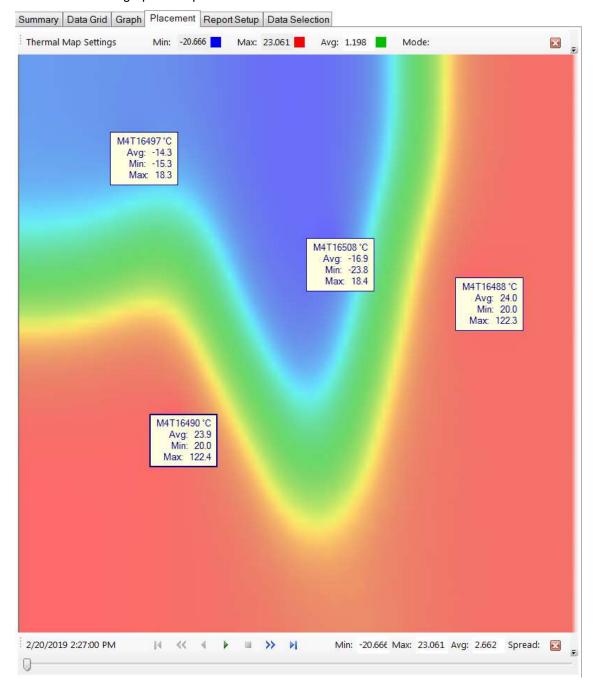


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5.2.4.5 Thermal Mapping

Selecting the Thermal Map option will open the Time Controls bar (if not already displayed) at the bottom of the Placement window and display a graphical representation of the heat distribution of the selected data.





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The Time Controls bar allows the user to review the heat distribution of the study.

- 5.2.4.5.1 The button starts the study and can be used to increment the study forward one interval.
 5.2.4.5.2 The button causes the study display to be revered and can be used to increment the study back one interval.
- 5.2.4.5.3 The button stops the study.
- 5.2.4.5.4 The button also starts the study and can be used to increment the study forward one interval. It also increases the speed that the study is displayed.
- 5.2.4.5.5 The button causes the study display to be revered and can be used to increment the study back one interval. It also increases the speed that the study is displayed.
- 5.2.4.5.6 The button cause the study to go directly to the end of the study.
- 5.2.4.5.7 The button cause the study to go directly to the beginning of the study.

The Thermal Map or Time Control bar can be removed by clicking on the right side of the window.

Notes:

- The Placement diagram can be printed or previewed using the Current View print icons located in the upper left corner.
- The Placement diagram can be included in a report, refer to Section 5.2.5.2 for additional details.



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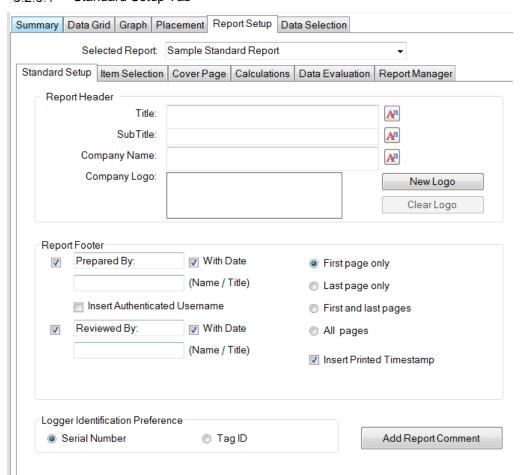
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5.2.5 Report Setup Tab

The Report Setup Tab is used to define the setup of Reports and Report Templates. The Report Setup Tab consists of 6 Tabs, each of which contains different settings for the Report Setup.

Report Templates can be selected from the Selected Report Drop Down menu, refer to Section 0 for additional details.

5.2.5.1 Standard Setup Tab



Note:

- Only the Logger Identification Preference is required to be entered on the Standard Setup Tab.
- Using the button can be used to change the Font options for individual items.



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5.2.5.1.1 Report Header

5.2.5.1.1.1 Title

The Title of the report that will be displayed on the Top Left of the printed Report Header.

5.2.5.1.1.2 Sub-Title

Additional Information that will be displayed below the Title on the printed Report Header.

5.2.5.1.1.3 Company Name

The Company Name can be included in the Top Right of the printed Report Header.

5.2.5.1.1.4 Company Logo

A *.bmp, *.jpg, or *.gif file can be added to the Report Header using the New Logo option. The file can be removed from the Report Header using the Clear Logo option.

5.2.5.1.2 Report Footer

5.2.5.1.2.1 Signature Lines

Up to 2 signature lines can be added in the Report Footer, by checking the box on the left of the Report Footer box.

The Signature Lines can be customized by the user. The default Signature Lines are Prepared By and Reviewed By.

The Signature Lines can be set to be printed on the first page of the report only, the last page of the report only, the first and last pages of the report, or on all pages of the report.

A time stamp of when the report was printed can also be included in the Report Footer, by selecting the Insert Printed Timestamp option.

5.2.5.1.2.2 Insert Authenticated Username

If the DT Pro Authentication or Regulatory Compliant System Security Setting is used, the user name of the person currently logged into the DT Pro software can be automatically added as the first signature line by selecting the Insert Authenticated Username option.

Refer to Section 2.2.1 for additional details.

5.2.5.1.3 Logger Identification Preference

The way the Data Loggers are displayed in the report can be set to be either Serial Number or Tag ID. Refer to Section 2.5.1.2 for additional details.



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5.2.5.1.4 Report Comments

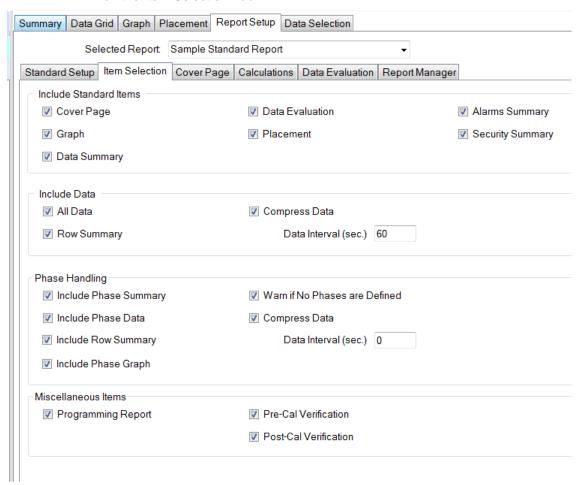
Additional comments can be added to the report as the first page of the Report by selecting the Add Report Comment option. The Report Comment window will open, and the user can add text or images that will be included in the printed report.

If an image is added the user can switch between the text and image by selecting either View Image or View Comment.

The added text or image can be removed by selecting either Clear Image or Clear Text.

5.2.5.2 Item Selection Tab

The items that are included in the printed report are selected from the options on the Item Selection Tab.





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| 5.2.5.2.1 Standard Items | | |
|--------------------------|---|--|
| 5.2.5.2.1.1 | Cover Page | |
| | The first page of the printed report will be the Cover Page. Refer to Section 0 for additional details. | |
| 5.2.5.2.1.2 | Graph | |
| | The Graph of the data as prepared in the Graph Tab will be included in the printed report. Refer to Section 0 for additional details. | |
| 5.2.5.2.1.3 | Data Summary | |
| | The summary of the data will be included in the printed report. Refer to Section 5.2.1 for additional details. | |
| 5.2.5.2.1.4 | Data Evaluation | |
| | The results of the Data Evaluation will be included in the printed report. Refer to Section 0 for additional details. | |
| 5.2.5.2.1.5 | Placement | |
| | The Data Logger Placement and Thermal Map (if applicable) will be included in the printer report. Refer to Section 5.2.4 for additional details | |
| 5.2.5.2.1.6 | Alarms Summary | |
| | A summary of the alarms that occurred during the study will be included in the printed report. Refer to Section 2.5.2 for additional details. | |
| 5.2.5.2.1.7 | Security Summary | |
| | A summary of the Security information will be included in the printed report. | |

The Security Summary includes:

- Security Detail
 - Security Mode to create the report.
 - User account and computer information used to create the report
- Report Detail
 - Report Template Name
 - The user who last edited the selected Template and the date and time it was edited.



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- Data Selection Detail
 - Data selection mode (By Study or Manual)
 - Study Name (if applicable)
 - Study Type (if applicable)
 - Data Start and End Date/Time
 - Excluded or manipulated data
- Logger Security Detail
 - Data Logger ID (Serial Number or Tag ID)
 - If the Data Logger was Validated
 - The User who Programmed the Data Logger
 - The User who Read the Data Logger.

5.2.5.2.2 Data

5.2.5.2.2.1 All Data

Includes the Data Grid in the printed report. Refer to Section 5.2.2 for additional details.

5.2.5.2.2.2 Row Summary

Include the Row Summary Data Grid in the printed report. Refer to Section 5.2.2 for additional details.

5.2.5.2.2.3 Compress Data

Is only available if either All Data or Row Summary have been selected.

If Compress Data is selected the printed report will include the specified data.

For example, if data was logged at 10 second intervals and the data is compressed to 60 seconds only one of every six data points will be included in the printed report.

Notes:

- The data interval unit (i.e. seconds, minutes, or hours) is set in System Setup, refer to Section 2.1.2 for additional details.
- Data compression can result in the inadvertent omissions if different data logging intervals are included in the selected data.
- If Data Summary is included in the Report, it will be included all of the selected data and not only the compressed data.



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| 5.2.5.2.3 Phase H | andling | |
|---------------------|---|--|
| 5.2.5.2.3.1 | Include Phase Summary | |
| | A summary of the data for each phase will be included in the printed report. | |
| 5.2.5.2.3.2 | Include Phase Data | |
| | The data for each phase will also be included in the printed report. | |
| 5.2.5.2.3.3 | Include Row Summary | |
| | The Row Summary of the phase data for each phase will also be included in the printed report. | |
| 5.2.5.2.3.4 | Include Phase Graph | |
| | A Graph for each defined phase will also be included in the printed report. | |
| 5.2.5.2.3.5 | Warn if no Phases are defined | |
| | Generates a warning message (with option to Cancel) if an attempt is made to print the report when no phases have been defined. | |
| 5.2.5.2.3.6 | Compress Data | |
| | Is only available if either Include Phase Data or Include Row Summary have been selected. | |
| | If Compress Data is selected the printed report will include the specified data. | |
| | For example, if data was logged at 10 second intervals and the data is compressed to 60 seconds only one of every six data points will be included in the printed report. | |
| | Notes: | |
| | The data interval unit (i.e. seconds, minutes, or hours) is set in System Setup, refer to Section 2.1.2 for additional details. | |
| | The phase data can be compressed at the same interval or a different interval than was used to compress all of the data. | |
| | Data compression can result in the inadvertent omissions if different data logging intervals are included in the selected data. | |
| 5.2.5.2.4 Miscellar | neous Items | |
| 5.2.5.2.4.1 | Programming Report | |
| | The Data Logger programming report will be included in the printed report. | |
| 5.2.5.2.4.2 | Pre-Cal Verification | |



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The most recent calibration reports prior to the start of the study for the selected Data Loggers will be included in the printed report.

5.2.5.2.4.3 Post-Cal Verification

The most recent calibration reports after the study was completed for the selected Data Loggers will be included in the printed report.



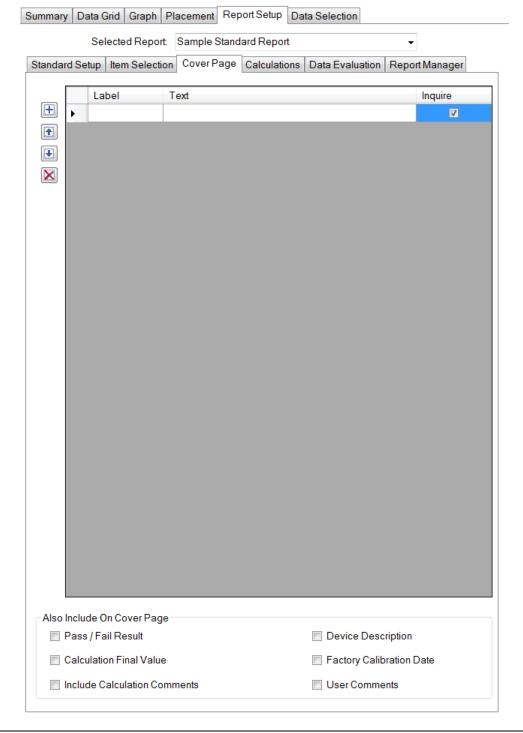
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5.2.5.3 Cover Page Tab

The Cover Page Tab is used to customize the cover page of a report.

Typical items included on the Cover Page include: a client or department name, address or contact information, a test protocol information, standard operating procedure information, or process information, test equipment calibration information, results or data from additional tests performed, or comments about the test and deviations noted.





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5.2.5.3.1 Default Items

The Cover Page will always include a list of the Data Loggers used in the study, the Data Logger start time, the logging interval, the Run ID, and Phase details (if applicable).

5.2.5.3.2 User Defined Text

The User can add text to customize the Cover Page.

| 5.2.5.3.2.1 | Use the button to create a new row. Text can then |
|-------------|---|
| | be entered into the Label and/or Text Columns. |

5.2.5.3.2.2 Use the button to remove a row.

(2000)

| 5.2.5.3.2.3 | Highlighting a row and using the and w | /ill |
|-------------|--|------|
| | move the selected row up or down the Cover Page. | |

5.2.5.3.2.4 Blank rows can be added to create additional space between rows of text.

5.2.5.3.3 Inquire

If the Inquire option is checked for a row, a text box will open when the report is printed or previewed, and the user will be required to enter the information for the row.

Note:

 The typical use for data inquiry is to require the report user to enter information such as the ID of test equipment used, a protocol name, the vessel or autoclave under test, some other process identifier or additional test results.

5.2.5.3.4 Additional Items

The user can select to include additional items on the Cover Page

5.2.5.3.4.1 Pass / Fail Result

If selected, the Data Evaluation results will be included on the Cover Page. Refer to Section 0 for additional details

5.2.5.3.4.2 Calculation Final Value

If selected, the Final Value of a Calculation will be included on the Cover Page.

Only applies to calculations that produce a final value (e.g. MKT or Lethality calculations). The calculation must also be selected in the Calculations Tab. Refer to Section 5.2.5.4 for additional details.

5.2.5.3.4.3 Include Calculation Comments

If selected, any comments entered in the System Setup for the selected calculation(s) will be included on the Cover Page. Refer to Section 2.1.4 for additional details.



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5.2.5.3.4.4 Device Description

If selected, the Serial Number, Tag ID, and Description for the selected Data Loggers in Device Configuration will be included on the Cover Page. Refer to Section 2.5.1 for additional details.

5.2.5.3.4.5 Factory Calibration Date

If selected, the Serial Number, Tag ID, and the Date of Factory Calibration for the Data Loggers will be

included on the Cover Page.

The Serial Number and Tag ID will not be repeated if

Device Description is also selected.

5.2.5.3.4.6 User Comments

If selected, all comments entered during the Programming or Reading of a Data Logger will be

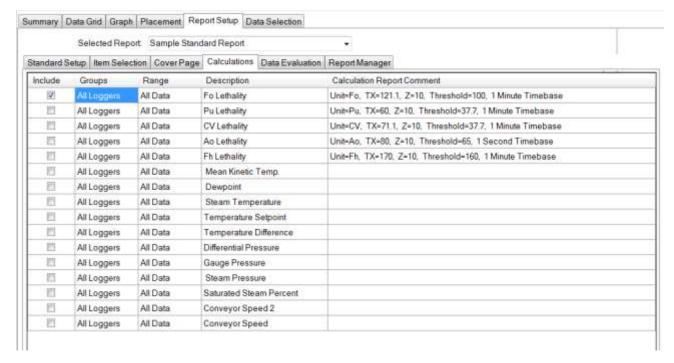
included on the Cover Page.

Notes:

- The Cover Page can be printed or previewed using the Current View print icons located in the upper left corner.
- The Cover Page can be included in a Report, refer to Section 5.2.5.2 for additional details.

5.2.5.4 Calculations Tab

The Calculations Tab is used to define which calculations will be included in the printed report. The table shows the available calculations and comments defined for that calculation.

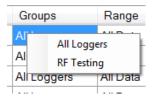




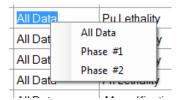
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- 5.2.5.4.1 Select the Include column for the calculation to include the calculation results in the printed report.
- 5.2.5.4.2 Selecting the Groups cell for a calculation will display a menu the user can use to select a Groups the calculation will apply to.



5.2.5.4.3 Selecting the Range cell for a calculation will display a menu the user can use to select a Phase that the calculation will apply to.



- 5.2.5.4.4 There is no limit to how many calculations can be selected.
- 5.2.5.4.5 The result of calculations that produce only a final value (e.g. Mean Kinetic Temperature) will be displayed in the Device Summary section of the printed Report if included in the Report.
- 5.2.5.4.6 The result of calculations that update with each data point (e.g. Lethality) will be displayed in the Data Grid section of the printed report, if included in the Report. Refer to Section 5.2.5.2.2 for additional details.
- 5.2.5.4.7 The result of calculations that produce both a final result and updating results (e.g. Lethality calculations) will be displayed in both sections.
- 5.2.5.4.8 Once a calculation has been selected for a report, it will by default be performed for all Data Loggers of the required data type.

If calculations do not need to be performed for one or more Data Loggers, the calculation can be individually disabled for a Data Logger in the Data Grid Tab. Refer to Section 5.2.2 for additional details.

5.2.5.4.9 Calculation Report Comments can be included in the printed report on the Cover Page. Refer to Sections 2.1.4 and 0 for additional details.



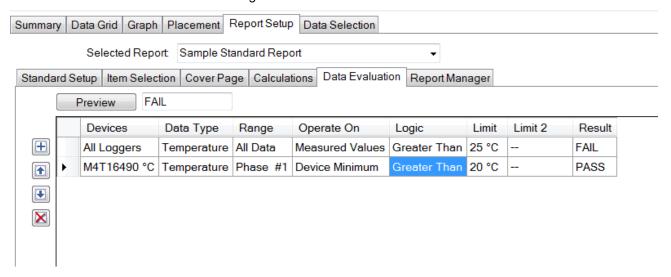
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5.2.5.5 Data Evaluation Tab

The Data Evaluation Tab is used to define logical operations that generate a Pass or Fail result for the data set.

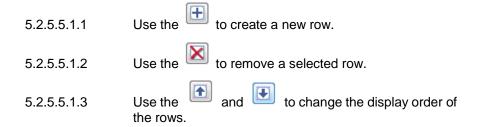
The conditions are defined within the rows of the evaluation grid. Each row is a test case which generates a Pass or Fail result.



Notes:

- It is best to have selected a study or data set before defining the logical conditions.
- The Preview button can be used to test the logic definition or obtain a preliminary Pass / Fail result. In order to preview, data must have been selected.
- To select or edit an item, click on the grid cell.
- The printed Data Evaluation page includes the results for each row.

5.2.5.5.1 Row Controls



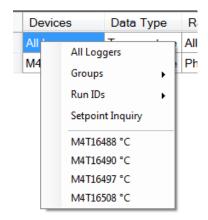


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5.2.5.5.2 Devices Column

Selecting the Devices Column cell for a row will display a menu that the Devices or Data Loggers that the Data Evaluation will apply to can be selected.

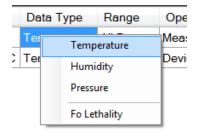


The Devices used for the Data Evaluation can be set to All Loggers, Groups, or Individual Loggers (selected using either the Data Logger Run ID or Serial Number).

Setpoint Inquiry can also be selected from the Device Column cell. If Setpoint Inquiry is used for Data Evaluation, the user will be prompted to enter the Setpoint after Setpoint Inquiry is selected.

If a Setpoint Inquiry row is added, it cannot be changed, and the row must be deleted to remove it from the Data Evaluation.

5.2.5.5.3 Data Type Column



Selecting the Data Type Column cell for a row will display a menu that the type of data (Temperature, Humidity, or Pressure) that the Data Evaluation will apply to can be selected.

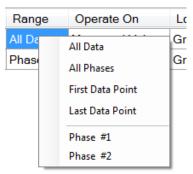
If a calculation has been selected, it will also be displayed in the Data Type Column



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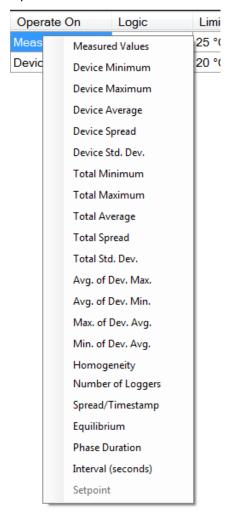
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5.2.5.5.4 Range Column



Selecting the Range Column cell for a row will display a menu that the period (All Data, All Phases, First Data Point, Last Data Point, or an Individual Phase) that the Data Evaluation will apply to can be selected.

5.2.5.5.5 Operate On Column





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Selecting the Operate On Column cell for a row will display a menu with the options about how the previously selected information will be evaluated.

| 5.2.5.5.5.1 | Measured Values |
|-------------|--|
| | Process the actual logged data values. |
| 5.2.5.5.5.2 | Device Minimum, Maximum, Average, Spread, or Standard Deviation |
| | Process the Device Summary values for the individual Data Loggers. |
| | Refer to Section 5.2.1.2 for additional Details. |
| 5.2.5.5.5.3 | Total Minimum, Total Maximum, Total Average, Total Spread, Total Std. Dev., Avg. of Dev. Max., Avg. of Dev. Min., Max. of Dev. Avg., Min. of Dev. Avg., or Homogeneity |
| | Process the Grand Total Summary values for the entire group. |
| | Refer to Section 5.2.1.1 for additional Details. |
| 5.2.5.5.5.4 | Number of Loggers |
| | The number of temperature Data Loggers in the selected data can be used to evaluate the data. |
| 5.2.5.5.5 | Spread / Timestamp |
| | The spread between Data Loggers at any one time can be used to evaluate the data. |
| 5.2.5.5.5.6 | Equilibrium |
| | The time difference between the first and last Data Loggers of a group to reach a setpoint can be used to evaluate the data. |
| 5.2.5.5.5.7 | Phase Duration |
| | The difference between the start and end time of a phase can be used to evaluate the data. |
| 5.2.5.5.5.8 | Interval |
| | The programmed data logging interval can be used to evaluate the data to determine if the study was completed as required. |
| 5.2.5.5.5.9 | Setpoint |
| | When the calculation is evaluated, a window will open asking for a Setpoint to be entered. Subsequent rows can then be defined to evaluate the data entered relative the entered Setpoint (e.g. the setpoint could be the expected temperature of a sterilization cycle, and |

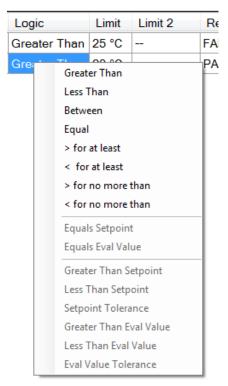
the subsequent rows could evaluate that the average temperature be within a defined range of the Setpoint).



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5.2.5.5.6 Logic



Selecting the Logic Column cell for a row will display a menu that defines the logical operation that will be applied to the previously selected information based on the defined limit(s).

| 5.2.5.5.6.1 | Greater Than |
|-------------|--|
| | The selected data must be greater than the defined limit for a Passing result. |
| 5.2.5.5.6.2 | Less Than |
| | The selected data must be less than the defined limit for a Passing result. |
| 5.2.5.5.6.3 | Between |
| | The selected data must be between to two defined limits (equal to the limit is a Fail condition) for a Passing result. |
| 5.2.5.5.6.4 | Equal |
| | The selected data must be equal a defined set-point for a Passing result. |
| 5.2.5.5.6.5 | > for at Least |
| | The selected data must be greater than a defined limit for a defined minimum amount of time for a Passing result. |



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| | 5.2.5.5.6.6 | < for at L | east |
|--|--------------|------------------------------------|---|
| | | | cted data must be less than a defined limit for a ninimum amount of time for a Passing result. |
| | 5.2.5.5.6.7 | > for no r | nore than |
| | | | cted data cannot exceed a defined limit for n a defined amount of time for a Passing |
| | 5.2.5.5.6.8 | < for no | more than |
| | | | cted data cannot be less than a defined limit than a defined amount of time for a Passing |
| | 5.2.5.5.6.9 | Equals S | etpoint and Equals Eval Value |
| | | | nt or Evaluation Value can be defined from ts of the Devices, Range and Operate On |
| | | Value eq | be used to enter a Setpoint or Evaluation ual to the Steam Temperature calculated by a Data Logger during a defined phase. |
| | | Total Ave Dev. Max of Dev. A | als Setpoint and Equals Eval Value options available if Total Minimum, Total Maximum, erage, Total Spread, Total Std. Dev., Avg. of x., Avg. of Dev. Min., Max. of Dev. Avg., Min. avg., Homogeneity or Number of Loggers are from the Operate On column. |
| | 5.2.5.5.6.10 | additiona | Setpoint or Evaluation Value has been defined, Il rows can be added to evaluate data based on pint or Evaluation Value entered. |
| | 5.2.5.5.6. | 10.1 | Greater Than Setpoint |
| | | | The selected data must be greater than the entered Setpoint for a Passing result. |
| 5.2.5.5.6.10.2 5.2.5.5.6.10.3 5.2.5.5.6.10.4 5.2.5.5.6.10.5 | | 10.2 | Less Than Setpoint |
| | | | The selected data must be less than the entered Setpoint for a Passing result. |
| | | 10.3 | Setpoint Tolerance |
| | | | The selected data must be within a defined range (Setpoint ± entered value) for a Passing result. |
| | | 10.4 | Greater Than Eval Value |
| | | | The selected data must be greater than the Evaluation Value for a Passing result. |
| | | 10.5 | Less Than Eval Value |
| | | | The selected data must be less than the entered Evaluation Value for a Passing result. |
| | | | |



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5.2.5.5.6.10.6

Eval Value Tolerance

The selected data must be within a defined range (Evaluation Value ± entered value) for a Passing result.

Note:

- Setpoint and Evaluation Values are stored as numbers without units of measure and it is possible to define illogical requirements (i.e. average humidity equals a temperature maximum)
- Multiple Setpoint inquiries or Evaluation Value definitions can be created; however the order they are arranged can affect the results. The order the results are analyzed is from top to bottom, The row order can be changed by selecting the row

and using



to move the row.

5.2.5.5.7 Limits

The Limit and Limit 2 columns are used to enter the values that the Data Evaluation will be based on.

Notes:

- The Data Evaluation results can be printed or previewed using the Current View print icons located in the upper left corner.
- The Data Evaluation results can be included in a report, refer to Section 5.2.5.2 for additional details.

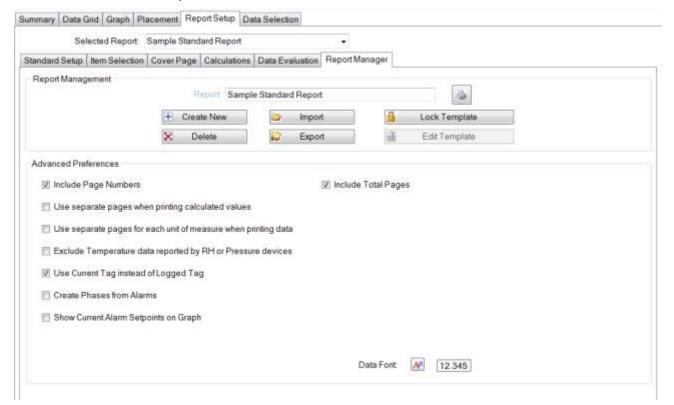


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5.2.5.6 Report Manager Tab

The Report Manager Tab allows the creation and customization of Report Templates.



5.2.5.6.1 Report Management

5.2.5.6.1.1 Report

The name of the Report Template can be entered or edited using the Report field.

5.2.5.6.1.2 Create New

A copy of the selected Report Template can be created by selecting the Create New option. The name of the Report Template can then be edited as required in the Report field.

5.2.5.6.1.3 Delete

The selected Report Template can be deleted by selecting the Delete option. If there is only one Report Template created, the Delete button will not be available.

5.2.5.6.1.4 Import

Report Templates created using a separate instance of DT Pro can be imported to a different DT Pro instance by selecting the Import option and then selecting the location of the Report Template Definition file (*.rpt)



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| 5.2.5.6.1.5 | Export |
|--------------------|--|
| | Report Templates can be exported as Report Template Definition files (*.rpt) that can then be imported into different DT Pro instances. |
| 5.2.5.6.1.6 | Lock Template |
| | Changes to the selected Report Template can be prevented by selecting the Lock Template option. |
| 5.2.5.6.1.7 | Edit Template |
| | Report Templates that have been locked can be edited by selecting the Edit Template option. |
| 5.2.5.6.2 Advanced | d Preferences |
| 5.2.5.6.2.1 | Include Page Numbers |
| | The page number will be included in the Report footer. |
| 5.2.5.6.2.2 | Include Total Pages |
| | The total number of pages will be included in the Report footer. |
| 5.2.5.6.2.3 | Use separate pages when printing calculated values |
| | Calculation results will be included on separate pages if this option is selected. If this option is not selected the results will be displayed after the data. |
| 5.2.5.6.2.4 | Use separate pages for each unit of measure when printing data |
| | Temperature, Relative Humidity, and Pressure data will be printed on separate pages if this option is selected. |
| 5.2.5.6.2.5 | Exclude Temperature data reported by RH or Pressure devices |
| | Relative Humidity and Pressure Data Loggers collect temperature data be default, if this option is selected, the temperature data for these Data Loggers will not be included in the report. |
| 5.2.5.6.2.6 | Use Current Tag instead of Logged Tag |
| | If a Tag ID is changed or assigned after data logging has begun, selecting this option will include the current Tag in the report. Refer to Section 2.5.1 for additional details. |
| 5.2.5.6.2.7 | Create Phases from Alarms |
| | Phase can be created for any alarm event that occurred during the study. The alarm start and end times will be the phase start and end times. Refer to Sections 2.5.2, 5.2.2 and 0 for additional details. |
| 5.2.5.6.2.8 | Show Current Alarm Setpoints on Graph |
| | |



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Alarm setpoints for each Data Logger will be shown on the Graph.

Showing the Alarm Setpoints can affect the way data is displayed on the Graph.

5.2.5.6.2.9 Process data and graphs by Group

Selected data printouts, summaries, or graphs will be generated for each Group included in the selected data. More than one Group must be included in the selected data for this option to be effective.

5.2.5.6.2.10 Data Font

A 12.345

The font and font size used in the Report can be set using this option.

5.2.5.6.2.11 Pressing will display or print a summary of the selected Report Template settings.

5.3 Calibration Reports

Selecting Calibration from the Reports Menu will open a window displaying all of the completed Calibration Reports. Clicking on the Select button for a Report will open the Calibration Report.

6.0 CALIBRATING LOGGERS

Calibration is the act of quantifying the accuracy of a measurement compared to a known reference standard. DT Pro provides two utilities for calibration. The user can check (verify) the accuracy of a Data Logger or adjust the device so that it more closely agrees with the reference standard.

Selecting the Calibration menu on the Test and Calibration window brings up three options for Data Logger calibration.

6.1 Restore Factory Defaults

This utility is provided to restore the calibration coefficients of the most recent factory calibration. If the Data Logger has two channels (e.g. temperature and humidity), both channels will be restored.

Note:

 The Restore Factory Defaults option does not affect or restore Cryogenic Temperature (-80°C) calibration coefficients.

6.2 Standard Calibration

Note:

• If your system has been configured to use only Environmental Monitors, the Standard Calibration utility will not be available.

The standard calibration utility is a simple to use 1 or 2 point calibration check or adjustment utility. Reference data is obtained through external means and manually entered by the user.

Data Logger adjustment is made via an offset correction (1 point mode) or a slope and offset correction (2 point mode).



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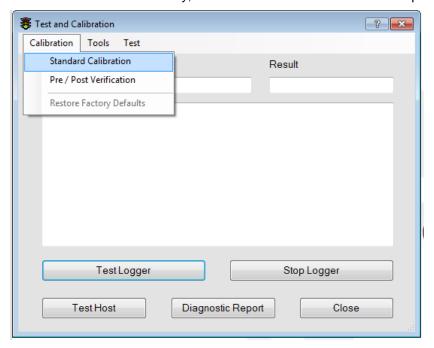
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The standard calibration utility can calibrate Data Logger models which support field calibration (MPIII Temperature, MPIII RH, MPRF Temperature, and MPRF RH).

This utility also includes a Cryogenic Calibration (-80° C) option for MPRF Data Loggers that possess this measurement range.

6.2.1 Standard Calibration Procedure

- 6.2.1.1 Program the Data Loggers to be calibrated to acquire data at a maximum of 1 minute intervals. Refer to Section 3.1 for additional details.
- 6.2.1.2 Place the Data Logger in the controlled environment with the Reference Instrument. Allow sufficient time for the readings to stabilize (stabilization typically takes between 15-30 minutes, but temperatures below -50°C may require additional stabilization time.
- 6.2.1.3 If a 2 point calibration is to be performed, once the Data Logger has been allowed to stabilizer and record the first reference point, place the Data Logger in the 2nd controlled environment with the Reference Instrument, and allow the Data Logger to stabilize and record the 2nd point.
- 6.2.1.4 After all Data Logger and Reference Instrument data has been acquired, open the Standard Calibration Utility, and follow the Calibration Wizard Steps.

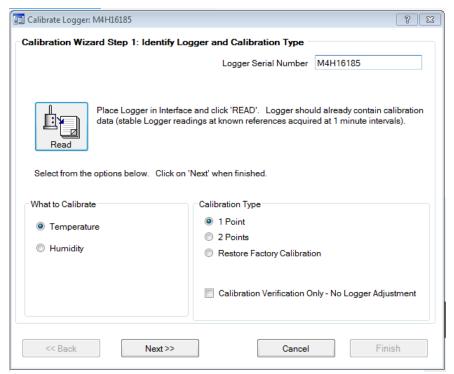


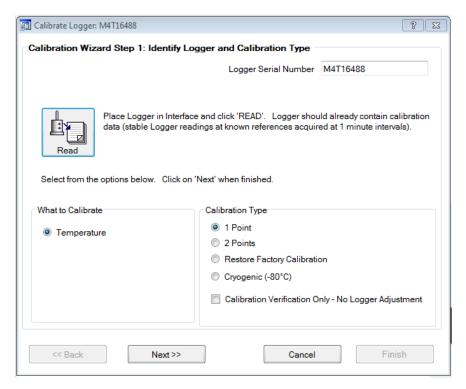


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6.2.1.5 Logger Calibration Wizard Step 1:







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6.2.1.5.1 Place the Data Logger in the PC Interface, choose the measurement type to calibrate and click the "Read" button.

Data collection is stopped once the Data Logger is read.

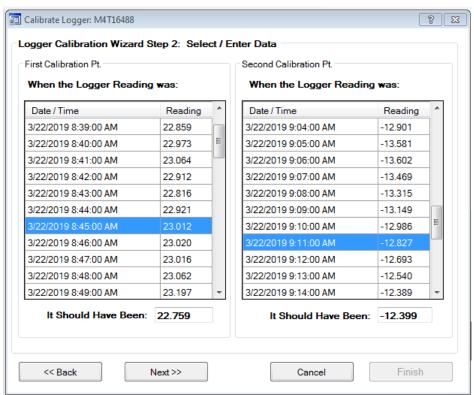
- 6.2.1.5.2 Select which reading type to calibrate.
- 6.2.1.5.3 1 Point, 2 Point, Restore Factory Calibration , or Cryogenic (-80° C).

The Cryogenic (-80°C) option is only displayed if the MPRF Data Logger is capable of being calibrated at that temperature.

- 6.2.1.5.4 Select the Calibration Verification Only option to verify the accuracy of the Data Logger readings. The Data Logger calibration coefficients will not be adjusted if this option is selected.
- 6.2.1.5.5 Select the Restore Factory Calibration option to restore the calibration coefficients of the most recent factory calibration.

If the Restore Factory Calibration option is selected, click Finish to restore the calibration coefficients of the most recent factory calibration.

- 6.2.1.5.6 Click Next.
- 6.2.1.6 Logger Calibration Wizard Step 2:



6.2.1.6.1 Select a data point after stabilization occurred for the Data Logger and Reference Instrument and enter the Reference Instrument reading at the selected time in the "It Should Have Been" field.

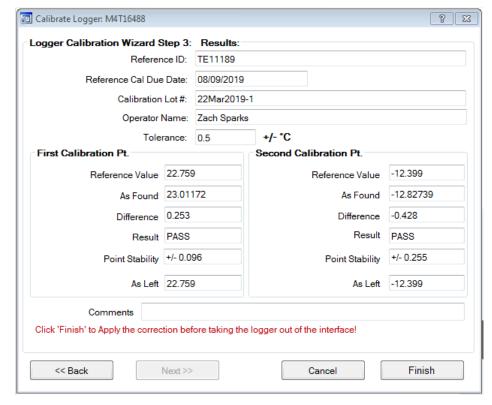
Repeat for the 2nd calibration point if necessary.



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6.2.1.7 Logger Calibration Wizard Step 3:



- 6.2.1.7.1 Enter the Results Information as required.
- 6.2.1.7.2 Review the calibration results.
- 6.2.1.7.3 Enter a Comment if desired, and then click Finish.

Notes:

- If the calibration was not a verification, new calibration coefficients will be loaded into the Data Logger.
- The calibration data will be saved, and a calibration report will be available, refer to Section 5.3 for additional details about creating calibration reports.
- The cryogenic (-80° C) calibration option is available only for MPRF Data Loggers that have had the cryogenic calibration option installed at the factory.

This routine calculates a correction factor that is applied only to temperatures below -40°C, without affecting the standard MPRF calibration range. It is implemented in a manner that presumes the Data Logger is accurate at -40°C.

The Restore Factory defaults option does not affect the cryogenic correction factor or restore it if it has been changed from the factory original value.



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6.3 Calibration Verification

Calibration Verification is commonly performed prior to or after validation testing. The resulting calibration reports can be printed separately or incorporated into the validation report and can be completed using user defined calibration profiles (e.g. defined setpoints, controls, evaluation criteria) or as a calibration adjustment utility.

Data can be automatically acquired by connecting the computer to the Reference Equipment (e.g. thermometer or temperature bath). Data can also be entered manually to complete the Calibration Verification.

Optional Data Logger or monitor adjustment is made via a best average offset correction (one setpoint) or a best fit (linear least squares regression) slope and offset correction (two or more distinct set-points).

- 6.3.1 Calibration Verification Setup
 - 6.3.1.1 Program the Data Loggers to that will be verified to acquire data at a maximum of 1 minute intervals. Refer to Section 3.1 for additional details.
- 6.3.2 Data Logger Selection

The Data Loggers that will be verified can be selected using a variety of methods.

- 6.3.2.1 Data Logger Group Calibration Verification.
 - From the Logger Functions menu, select the Programmed group, right-click on the Group, and selecting the Cal Verification option. Refer to Section 3.4.4 for additional details.
- 6.3.2.2 If wireless data is active, select a group or an individual Data Logger in the Wireless Data menu, right click on the Group, and selecting the Cal Verification option. Refer to Section 4.7.4 for additional details.
- 6.3.2.3 From the Configuration Tools menu, select a group or an individual Data Logger, right click for the options menu, and selecting the Cal Verification option. Refer to Section 2.5.7 for additional details.

This method requires Administrator or Power User access.

6.3.2.4 Once the Calibration Verification window is open, the Data Loggers to be verified are displayed on the left side of the Calibration Verification window.



A Data Logger can be removed by right clicking on the Data Logger and selecting Remove Device.





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6.3.2.5 If Cal Verification is selected for additional Data Loggers, and the verification window is already open, the Data Loggers will be added to the existing verification group.

Notes:

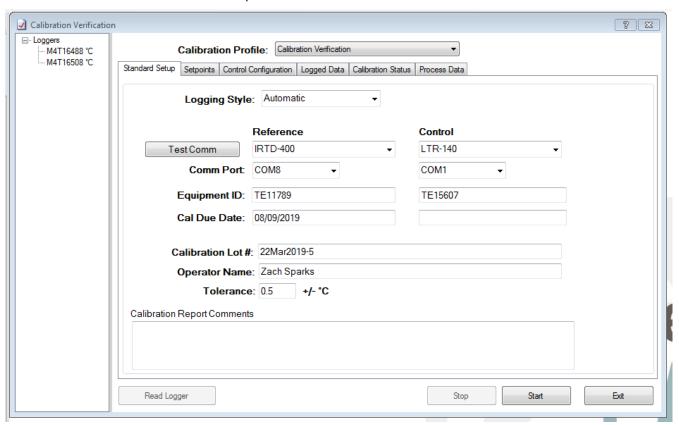
- Selecting Pre / Post Verification from the Calibration Menu in the Test and Calibration window will open the Calibration Verification window, but the Data Loggers must be selected using the Logger Functions, Wireless Data, or Configuration Tools menus.
- If real time Data Logger stability evaluation is desired (for MPRF Data Loggers), they
 must be included in the group and RF communications must be active.

6.3.3 Calibration Procedure

Pre-defined Calibration routines can be selected from the Calibration Profiles drop down menu box, and then clicking the Start button.

The Calibration Verification can also be setup as needed using the six tabs to define how the verification is performed, review the verification results, and also perform Data Logger adjustments. Pressing the Start button at anytime will begin the Calibration Verification procedure.

6.3.3.1 Standard Setup Tab



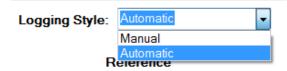
The Standard Setup Tab is used to define what equipment is connected to the computer, how it will be used, and how it will be identified in calibration reports and to define the Calibration Verification tolerance.



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6.3.3.1.1 Logging Style

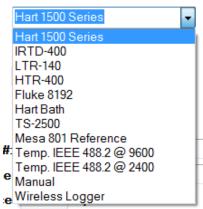


If Automatic is selected, the utility will issue set points to the control device, evaluate stability and log data per set point and control settings.

If Manual is selected, the user will decide when the reference data will be logged by manually clicking the Log Data button in the Calibration Status Tab.

6.3.3.1.2 Reference

Reference



Select the device which will provide the Reference Instrument readings when using the Automatic Logging Style.

6.3.3.1.2.1 If Manual is selected the user must select the measurement type and will enter the reference value in the Calibration Status Tab. Refer to Section 0 for additional details.



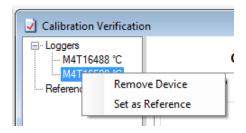
Note:

- The Manual option is displayed in the Reference drop down menu if Automatic Logging Style is selected, but it cannot be selected.
- 6.3.3.1.2.2 If Wireless Logger is selected, the reference Data Logger must be selected by right clicking on the Loggers list and selecting the Set as Reference option.



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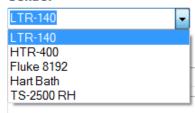




RF Data Reception must be turned on in order to use a Wireless Logger as the Reference.

6.3.3.1.3 Control

Control



Select the device which will control the environment the Data Logger is exposed to.

This selection will not be available if the Logging Style is Manual or the Reference also provides control of the conditions.

6.3.3.1.4 Comm Port

Define which port of the computer the Reference and Control are connected to.

6.3.3.1.5 Equipment ID

Enter how the Reference or Control will be identified on the Calibration Report.

6.3.3.1.6 Cal Due Date

Enter the Calibration Due Date for the Reference or Control that will be included on the Calibration Report.

6.3.3.1.7 Calibration Lot

Enter an identifier for the Calibration Verification that will be included on the Calibration Report.



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6.3.3.1.8 Operator Name

Enter the Name of the person performing the calibration.

If DT Pro Authentication or Regulatory Compliant System Security is used the Operator Name will be the person currently logged into DT Pro.

6.3.3.1.9 Tolerance

Enter the Pass / Fail tolerance for the Calibration Verification.

6.3.3.1.10 Comments

Additional information that will be included on the Calibration Report

Notes:

- Any changes made are saved as part of the currently selected calibration profile.
- New calibration profiles can be created in the Control Configuration Tab. Refer to Section 0 for additional details.

6.3.3.2 Setpoints Tab

The Setpoints Tab is used to define the set points for the Calibration Verification, the order they will occur, and the minimum soak time at each Setpoint.

These items are not applicable when using Manual Logging Style.

| 6.3.3.2.1 | Use and ko create or remove rows. |
|-----------|--|
| 6.3.3.2.2 | Use or to change the Setpoint order. |
| 6.3.3.2.3 | Enter the desired Setpoint in the Setpoint column. |
| 6.3.3.2.4 | For each Setpoint, also enter a minimum Soak time. |

Notes:

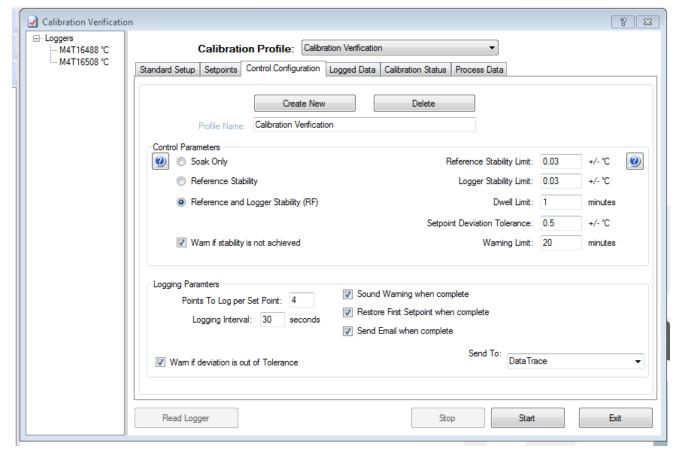
- The order of verification will be from the first row to the last.
- There is no inherent limit on the number of set points; if several calibration
 points need to be logged at each set point, use the Point To Log per Set
 Point option in the Control Configuration Tab rather than duplicating set
 points. Refer to Section Ofor additional details.
- If the Reference is set to Manual, place the Data Logger in the controlled environment with the Reference Instrument. Allow sufficient time for the readings to stabilize (stabilization typically takes between 15-30 minutes, but temperatures below -50°C may require additional stabilization time.



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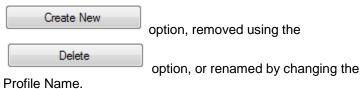
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6.3.3.3 Control Configuration Tab

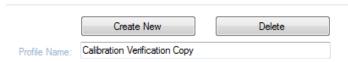


The Control Configuration Tab is used to configure how an automated verification proceeds, how and when a stable calibration data point is logged, and what happens when the process is finished.

6.3.3.3.1 Calibration profiles can be created using the



If a new profile is created and it is not renamed, it will be a copy of the previously selected profile.

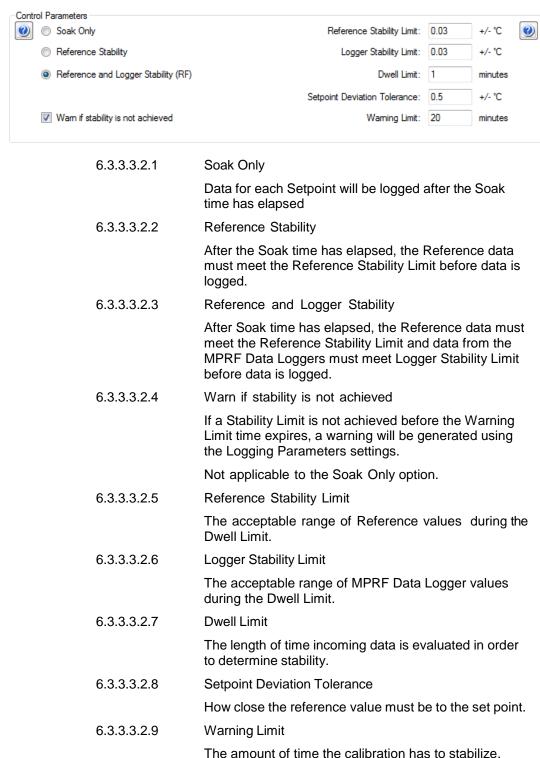




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6.3.3.3.2 Control Parameters





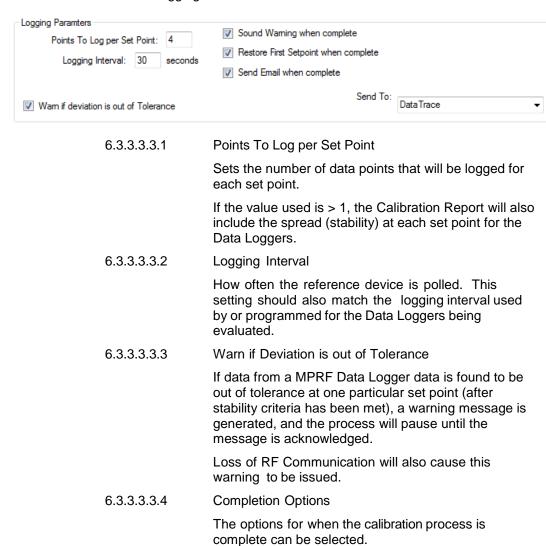
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Notes:

• If Reference Stability or Reference and Logger Stability are used, the Dwell Limit should be at least four times longer than the programmed logging interval.

6.3.3.3.3 Logging Parameters

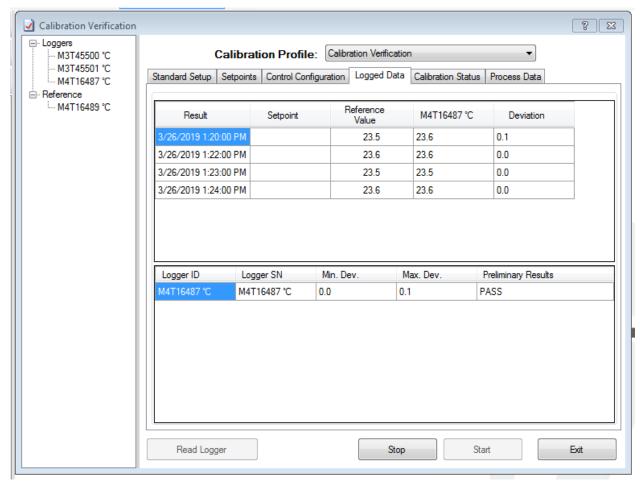




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6.3.3.4 Logged Data Tab



- 6.3.3.4.1 The top grid shows the data that has been logged and the result of tolerance evaluation for each Reference Data Point.
- 6.3.3.4.2 The bottom grid shows data for MPRF Data Loggers being evaluated, and the summary of the tolerance evaluation for all Reference Data Points.

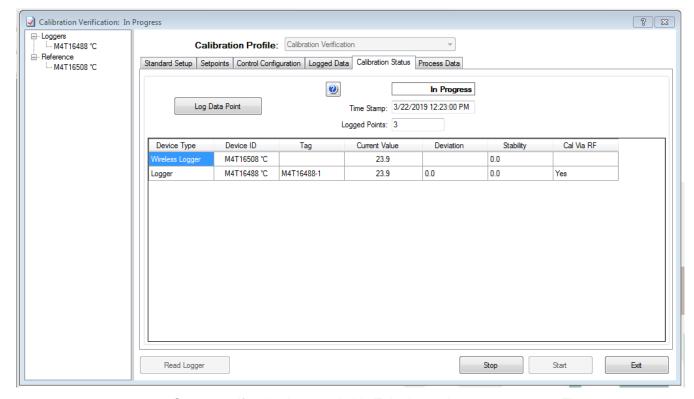
The bottom grid will also show the summary of the tolerance evaluation for MPIII Data Loggers after they have been Read.



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6.3.3.5 Calibration Status Tab

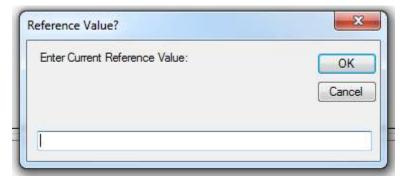


Once a verification is started, this Tab shows the process status: The current set point, reference device, MPRF Data Logger (if any) and stability (if specified) values are shown. The Values for devices that do not meet stability criteria (if specified) are displayed in red.

If Manual Logging Style is selected, a "Log Data Point" button will be visible after the Logging interval defined in the Control Configuration Tab has passed.



When using a Manual Reference, pressing the Log Data Point will open a window to enter the value for the Reference Data Point.



Pressing will switch the display between the detailed view and the data for the last data point received via RF.

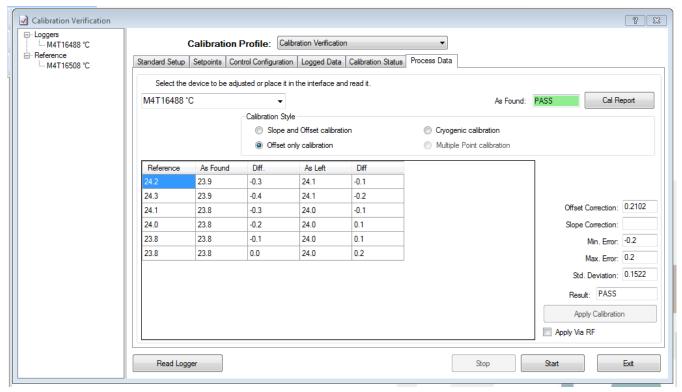


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6.3.3.6 Process Data Tab

The Process Data Tab provides tools to calculate and load adjustment parameters into Data Loggers.



After enough data has been recorded to meet the Soak time the calibration can be stopped, and the calibration can be applied.

6.3.3.6.1 MPRF Data Loggers

| 6.3.3.6.1.1 | The MPRF Data Logger can either be placed into the PC Interface and the Read Logger option selected or the Calibration Verification data can be obtained using RF. |
|-------------|--|
| 6.3.3.6.1.2 | Once the Data Logger has been read, its data will be automatically evaluated. The As Found box will indicate Pass or Fail relative to the specified Tolerance. |
| 6.3.3.6.1.3 | If the Calibration Verification has passed and the user wants to adjust the Data Logger calibration, press the Apply Calibration button. |
| 6.3.3.6.1.4 | Data Logger results (e.g. minimum and maximum errors) can also be seen in the Logged Data Tab. |



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6.3.3.6.2 MPIII Data Loggers

6.3.3.6.2.1 Ensure that enough stable Reference Data Points were logged. Refer to Section 0 if completing a Manual Calibration Verification.

6.3.3.6.2.2 Press the Stop button on the bottom of the Calibration Verification window.

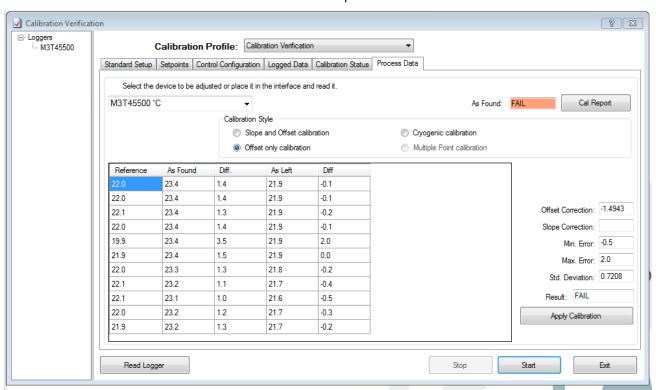
6.3.3.6.2.3 Place the Data Logger in the PC Interface.

6.3.3.6.2.4 Use the Read Logger button to retrieve the Calibration Verification data from MPIII Data Loggers.

The act of reading a Data Logger will cause it to be added to the verification group, its data will be evaluated, and a calibration report generated (if the results are acceptable, adjustment is not required).

Data collection will be stopped when the Data Logger is read.

6.3.3.6.2.5 The As Found box will indicate Pass or Fail relative to the specified Tolerance.



6.3.3.6.2.6 The Calibration Verification results can also be seen in the Logged Data Tab.



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6.3.3.6.3 Adjusting/Calibrating Data Loggers

6.3.3.6.3.1 If the Data Logger needs to be adjusted or calibrated, select the Calibration Style to use.

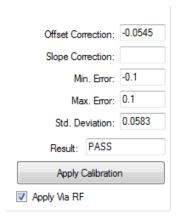
| Calibration Style | | | | |
|--|----------------------------|--|--|--|
| Slope and Offset calibration | Cryogenic calibration | | | |
| Offset only calibration | Multiple Point calibration | | | |

DT Pro uses a best fit linear regression to calculate the best adjustment.

If only one Setpoint was used, use the Offset only option.

If 2 or more Setpoints were used, and span the intended range of measurement, use the Slope and Offset calibration option.

6.3.3.6.3.2 The statistical results of the adjustment calculation are shown in the boxes on the left.



6.3.3.6.3.3 Select Apply Calibration to load the calibration adjustment into a Data Logger.

If selecting a MPRF Data Logger form the drop down box and using the Adjust Via RF option, RF communications must be active. It can take several logging intervals before the adjustment occurs. Refer to Section 4.3 for additional details.

6.3.3.6.4 Cal Report

6.3.3.6.3.4

The Calibration Reports for the entire group can be accessed using the Cal Report button in the top left of the Process Data screen. Calibration Reports can also be accessed by expanding the Reports Menu and selecting Calibration.

Calibration reports can also be included as part of a Report; either as a Pre-Process or Post-Process verification, refer to Sections 5.2.5.2 and 5.3 for additional details about creating Calibration Reports.



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6.3.4 Additional Calibration Considerations

- 6.3.4.1 DT Pro does not evaluate the quality or precision of references or the suitability of the reference or control equipment to be used for calibrations. A typical use for the Comments field is to document or describe the calibration system uncertainty or specifications of the equipment used.
- 6.3.4.2 It is highly recommended that after any adjustment, a second verification be performed to confirm the Data Logger readings.
- 6.3.4.3 There are minimal limits on how much a device can be adjusted; once an adjustment has been made, any previous certifications are no longer valid.
- 6.3.4.4 If a slope and offset adjustment is made, the calibrated range of the Data Logger should be considered to be from the minimum set point to the maximum set point.
- 6.3.4.5 Calibration drift is not necessarily linear, to effectively characterize MPIII or MPRF Data Loggers across their entire specified operating range, a minimum of four set points are required.
- 6.3.4.6 All temperature sensors are subject to error due to immersion depth. It is preferable to calibrate Temperature Data Loggers in a bath with the Data Logger submerged; alternatively, the sensor should be immersed a minimum of 4 to 6 inches. Best performance will be achieved if the body of the Data Logger is also near the temperature it will be during process measurements.

7.0 TROUBLESHOOTING

- 7.1 RF Data Reception
 - 7.1.1 Data is Not Displayed

Data that has been received by the DT Pro software, but is not being displayed in the Wireless Data Menu Data Grid, or Graph can be caused by:

- 7.1.1.1 Data will not be recorded if logging has been disabled for the Data Logger.Refer to Section 2.5.1 for additional Details.
- 7.1.1.2 If the Data Logger's internal time is off by more than one data logging interval due to extended periods of not communicating with the DT Pro software, received data will not be logged.
 - Moving the Data Logger closer to the MPRF PC Interface or Repeater will eventually synchronize the Data Logger with the system, and once this occurs, logged data and graphs will be available, and any missed data will be retrieved. Environmental Monitors are not able to be synchronized.
- 7.1.1.3 The Graph will not be displayed until at least 3 rows of data are available. This typically occurs at the beginning of RF studies when longer data transmission intervals.
- 7.1.1.4 If data is viewed using the Reports Menu, real time data is not displayed. Using the Wireless Data menu allows real time data to be viewed.



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7.1.2 Intermittent RF Data Reception

7.1.2.1 Multiple Groups of Data Loggers attempting to transmit data using the same RF Channel can decrease the RF transmission rate.

DT Pro will automatically take corrective action to ensure that all data is received, but it can require a significant amount of time depending on the communication status.

- 7.1.2.2 If the Data Loggers are using High Density Data Packaging or if the number of Data Loggers transmitting data is close to or exceeds the logging interval, the data will be transmitted every other interval, or every third or more depending on the number of Data Loggers. Missing data points will eventually be recovered by the software.
- 7.1.2.3 RF data reception can be intermittent or completely stop when the temperature of the Data Logger rapidly changes, or if the temperature of the Data Logger is > 125°C or < -40°C.

RF data reception can also be intermittent or completely stop if the temperature of the Data Logger probe is very different from the temperature of the Data Logger body, e.g. the Data Logger sensor if monitoring a sterilization cycle through a port while the Data Logger body is at room temperature. Selecting the "Logger body will be at ambient temperature" option during Data Logger programming can help minimize the issue.

- 7.1.2.4 RF data reception can be also be intermittent during Report Creation, Printing, Programming, Reading, or other user activities which require significant computational resources. Data will eventually be recovered.
- 7.1.3 Data is not received by the DT Pro software
 - 7.1.3.1 The Data Loggers were not programmed to use Radio.
 - 7.1.3.2 If more Data Loggers were programmed than the value entered for the "Number of Loggers in Group" setting in the Select MPRF Radio Options screen. The Data Loggers programming may have to be repeated.
 - 7.1.3.3 The Data Loggers were programmed for a different channel than the MPRF PC Interface or Repeater. Refer to Section 2.5.6 and 3.3.6.3 for additional details on setting the MPRF PC Interface channel.
 - 7.1.3.4 The MPRF PC Interface is not functional. The MPRF PC Interface consists of two distinct circuits; the RF circuit and the IR (infra-red) communications circuit.
 - The ability to program or read Data Loggers is not an indication that the RF circuit is working. The "Test Host" function checks that the RF circuit is communicating but does not check that the MPRF PC Interface is functional.
 - 7.1.3.5 The Data Logger battery has been reset, has insufficient charge or has been completely drained.

RF transmission requires much more power than data logging. When a Data Logger has a battery with insufficient power to transmit, it will cease all RF transmissions, but continue data logging. The radio reset condition will be identified when the Data Logger is read and the message "The radio was disabled due to low battery power during the last data acquisition cycle".

This condition can also occur when a Data Logger is used in cryogenic environments where battery performance is severely degraded. RF reception does not resume once the Data Logger is warmed and more power is available.



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Refer to Sections 0 and 3.3.6.1 for additional details on battery management.

7.1.3.6 The Data Logger is too close to the MPRF PC Interface (or is still in the MPRF PC Interface). When checking RF communications, the two devices should be at least 6 inches apart.

7.1.4 Environment and Distance

- 7.1.4.1 MPRF Data Loggers are specified to transmit data between 100-500 feet with no obstruction between the Data Logger and the MPRF PC Interface or Repeater. Walls, machinery, or other obstructions will reduce the distance that data can be transmitted.
- 7.1.4.2 Transmission of data from a metal chamber (e.g. oven, autoclave, or freezer) will require a non-metallic path for the RF signals. A rubber door gasket is typically sufficient, but the signal will be significantly weakened. It can be necessary to place the MPRF PC Interface, or a Repeater close to the path use an antenna which is inserted into the chamber and connected to the MPRF PC Interface or Repeater to receive data.
- 7.1.4.3 Whenever possible, avoid placing MPRF Data Loggers directly on metallic surfaces. Metallic surfaces can limit distance and create "blind spots" for the reception or transmission of signals from locations directly behind the metal surface.
- 7.1.4.4 The Data Logger's RF network is tolerant of other devices using the same channel; however, performance can improve by using a different channel.

7.2 PC Interface Communication

7.2.1 No Communication

- 7.2.1.1 Avoid placing the PC Interface in direct sunlight or other bright light. This can cause IR interference and cause communication problems.
- 7.2.1.2 Verify that the USB driver is properly installed.

7.2.2 Intermittent Communication

- 7.2.2.1 Any stickers or markings placed on the Data Logger body can interfere with communications.
- 7.2.2.2 The Data Logger is too hot or too cold. Communication can be enhanced is the Data Loggers are allowed to equilibrate to room temperature before attempting to Read it.
- 7.2.2.3 The Data Logger can require factory service is fluid or corrosion is observed inside of the Data Logger body.
- 7.2.2.4 As the MPRF PC Interface ages, the optical communication performance can begin to degrade. Using a different MPRF PC Interface can alleviate the communication issues.
- 7.2.2.5 Cleaning the Interface optical tube can increase the optical communication. Wipe out the MPRF PC Interface with a clean, lint free, and non-abrasive cloth.

The optical tube can be removed by carefully twisting and pulling it out of the MPRF PC Interface and inspected. The optical tube should be clear and transparent.



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7.3 Incorrect Data

Data Logger measurement errors are typically indicative of hardware failure and will require factory service.

7.3.1 Relative Humidity Measurement Errors

- 7.3.1.1 The RH sensor is loose or making intermittent contact. If the sensor is loose, remove the sensor from the Data Logger body, use needle nose pliers or tweezers to put a small bend (about 30° angle) in the legs of the sensor and reinsert the sensor.
- 7.3.1.2 The RH sensor was exposed to a condensing environment. Allow the sensor to dry off, and then use the Test Logger function to confirm accurate measurements prior to process use.
- 7.3.1.3 The RH sensor has been damaged by repetitive exposure to a corrosive environment such as Ethylene Oxide. When a Data Logger is used for RH monitoring during Ethylene Oxide sterilization, the RH sensor may need to be replaced or re-calibrated frequently.
- 7.3.1.4 Relative Humidity is dependent on temperature. If the temperature is changing rapidly, there can be significant difference between the RH inside the Data Logger's protective cover and the outside environment.
- 7.3.1.5 An inaccurate or unstable RH reference was used during a calibration or calibration verification.

7.3.2 Temperature Measurement Errors

- 7.3.2.1 The temperature sensor or other Data Logger hardware is damaged and will require factory service.
- 7.3.2.2 The temperature sensor was exposed to a condensing environment. Allow the sensor to dry off, and then use the Test Logger function to confirm accurate measurements prior to use.
- 7.3.2.3 An inaccurate or unstable reference was used during a calibration or calibration verification.

7.3.3 Pressure Measurement Errors

- 7.3.3.1 Older Pressure Data Loggers models can measure inaccurately (readings are off by 5 to 10 PSIA) when the battery is very low or weak.
- 7.3.3.2 Using Pressure Data Loggers at temperatures below 25°C can be outside of the defined calibration tolerance.

7.3.4 Missing Data

Some Data Loggers can experience a hardware problem that causes the Data Logger's internal clock to stop, causing the data to stop being recorded. Some possible causes are:

- 7.3.4.1 The Data Logger hardware is damaged and requires factory service.
- 7.3.4.2 The Data Logger body was exposed to a temperature ≥ 140°C.
- 7.3.4.3 The Data Logger's battery is low.



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7.4 Data Logger Reset

A Data Logger Reset condition can occur when power to the Data Logger power circuit is interrupted, the Data Logger battery is too low to perform a function, the Data Logger is damaged, or if an electrostatic discharge event.

If a Data Logger is recording data when the reset occurs, it will stop logging data and when the Data Logger is read only data up to the reset point will be available.

- 7.4.1 Changing the battery, or simply removing the battery cover.
- 7.4.2 Battery contacts are damaged or missing. This can be caused by corroded contacts, by the use of a non-approved battery, incorrect battery installation, mechanical shock, or other physical damage.
- 7.4.3 The battery level is lower than estimated.
- 7.4.4 The Data Logger power circuit is damaged and using too much energy. This condition can also cause incorrect data to be recorded.
- 7.4.5 The Data Logger was used with RF at ultra-low temperatures (≤ -40°C).

7.5 Database Troubleshooting

The Database Configuration Utility contains the tools required to set various database parameters such as physical location or local only versus shared (LAN) operation. It also contains diagnostic, recovery and backup tools.

Refer to Section 2.4 for additional details. If these tools cannot correct problems, contact Mesa Laboratories, Inc. Technical Services for assistance.

7.6 Reporting Software Problems

In the event of unresolved problems with the DT Pro software please contact Mesa Laboratories Inc. Technical Services at DTSupport@MesaLabs.com.

Please include the following information or have the information available when contacting technical support.

- Description of the Problem.
- Window or screen at which the problem occurs.
- DT Pro Software Revision (Help menu > About).
- Data Logger Type(s) in use.
- Computer Type.
- Computer Operating System.
- A Logger Diagnostic Report may be required. Refer to Section 3.3.4 for additional details.
- The ErrLog.txt file located in DT Pro's working directory (Typically: C:\Program Files\DataTrace Pro may be required.



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REVISION HISTORY

| Revision | Change Summary | Author | Date |
|----------|----------------|-----------|-------------|
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| Author (Print Name): Zacha-y Sparks | _ Title: Valio Sim Engineers | | | |
| (Sign Name): | Date: 06 Way 2019 | | | |
| Business Development (Print Name): Adam Reicher | t Title: BDM | | | |
| (Sign Name): | _ Date: _ 5-8-/9 | | | |
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| (Sign Name): Jeun heur | Date: 08 -NAY - 2019 | | | |