TRAINING MANUAL
FOR

DataTrace® Pro

v1.2

PRODUCED BY

MesaLabs

12100 W. 6th Ave.
Lakewood, CO USA

PREPARED BY:

KHOI NGUYEN & BRADLEY PICKARD
SENIOR SOFTWARE ENGINEER & DATATRACE PRODUCT MANAGER
MESA LABORATORIES, INC

Table of Contents

*****

Chapter 1: General Information

Mesa Laboratories' DataTrace Pro (DT Pro) Software is the heart of the DataTrace® MPRF and MPIII process monitoring solution. From the creation of process reports, analyzing and understanding data, and complying with your regulatory requirements, DT Pro gives you greater insight and productivity.

1.1 What's New in DataTrace Pro

- A new reporting engine which allows the creation of custom report templates, including new display options, types of calculations, pass / fail evaluations, cover page and signature line options, multiple methods for creating studies, selecting specific data ranges or loggers, and new tools for the efficient creation of phases or sub-summaries.
- The ability to organize loggers by creating groups, studies, or assigning ID tags to individual loggers.
- The ability to assign loggers a separate ID tag for each measured parameter.
- Alarm configuration and control, including high or low types, fault detection, calibration-due warnings, alarm reporting, email notification, alarm acknowledgement, escalation, and commenting.
- New automated calibration utility interfaces with different temperature references, baths or dry-wells and allows for pre- or post-process calibration verification or adjustment using multiple user defined set-points and parameters.
- New MS SQL Server Express database allows direct access (read only) to data for applications which support standard SQL data interfaces – no additional MS SQL Server licenses or fees are required.
- Support for a self-configuring, time-synchronized RF mesh network and AC powered router / repeaters.
- Support for continuous (FIFO) logging and GxP-compliant environmental monitoring.

1.2 DT Pro Editions

DataTrace Pro is available in four editions: Basic, Standard, Plus and LAN Server.

- **DataTrace Pro Basic**: Includes all the tools to program, read, test and calibrate 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.

- **DataTrace Pro Standard**: In addition to the features of the Basic edition, includes support for RF loggers and interfaces. The Standard edition is **NOT** 21 CFR Part 11 compliant.

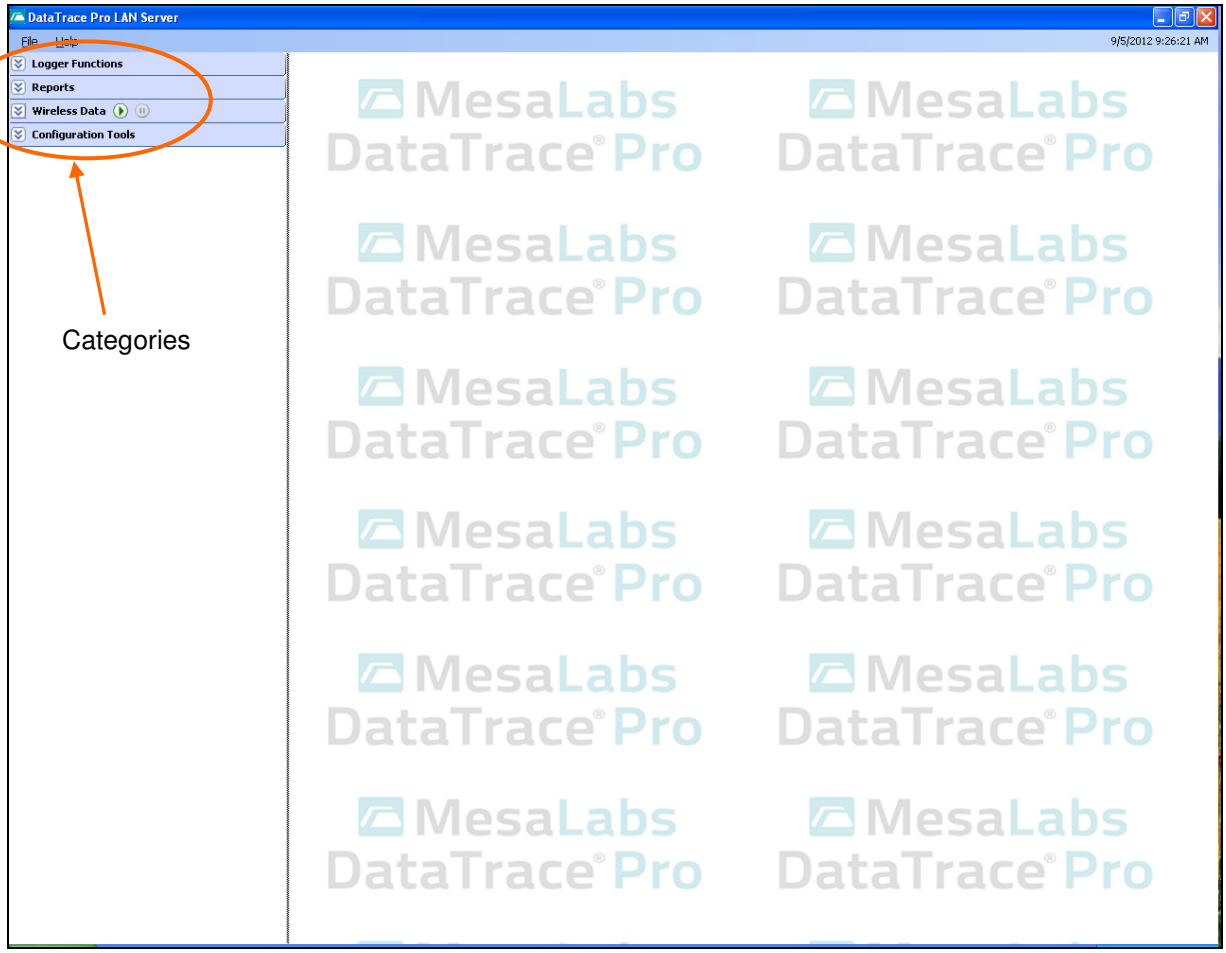
- **DataTrace Pro Plus**: In addition to the features of the Standard edition, includes support for regulatory compliance, wireless data reception and alarming functions.

- **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; Basic and Plus editions include the components necessary to connect to the LAN Server database.

Edition Upgrade: DT Pro may 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 (can bee seen in the Help > About DataTrace Pro window or in the System Setup Report). Once you have obtained the new code, to activate it go to the File menu, then click on License Registration. When the Edition Licensing window appears, enter in the new license code, and then click the Activate button to activate the new code.

1.3 Main categories

Most items and controls within DataTrace Pro's main window are intuitive, self-explanatory or conform to standard conventions. See screen shot below:

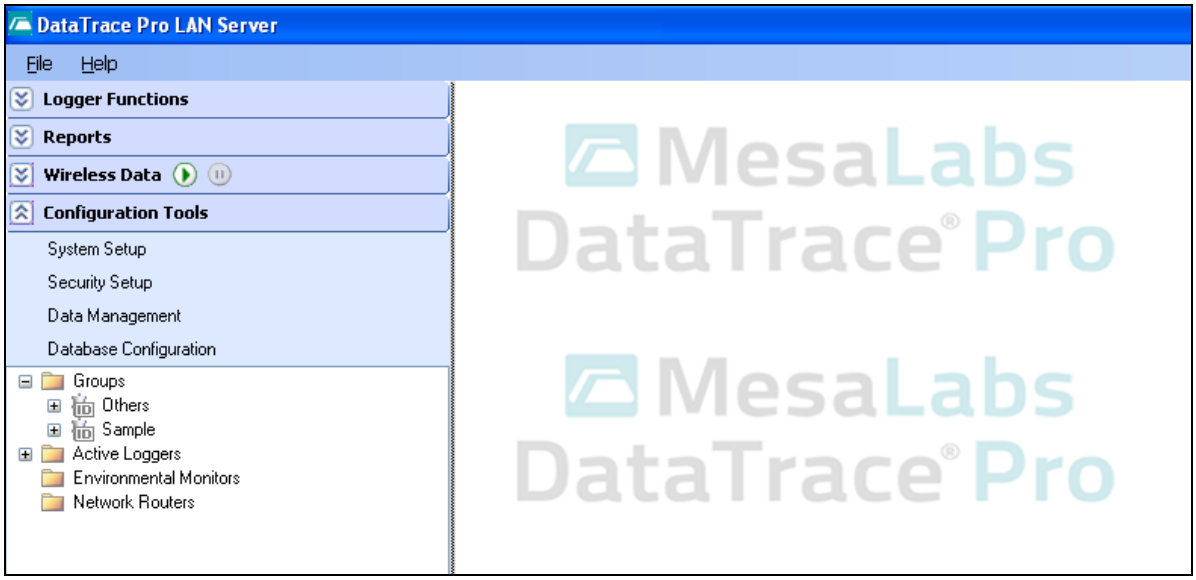


For many items, a right-mouse button click will expose a pop-up menu with additional options. The following is the basic steps needed to use the DataTrace system.

1.3.1 Configuration Tools

Left-click this category to setup and configure your DT Pro system will show the following items:

- System Setup: set units of measure, displayed decimal points, language, radio (or none) and other preferences
- Security Setup: set the security level, define users, permission levels, e-mail addresses and more.
- Data Management: import, export archive or delete data.
- Database Configuration: set data storage options (local or LAN/server)



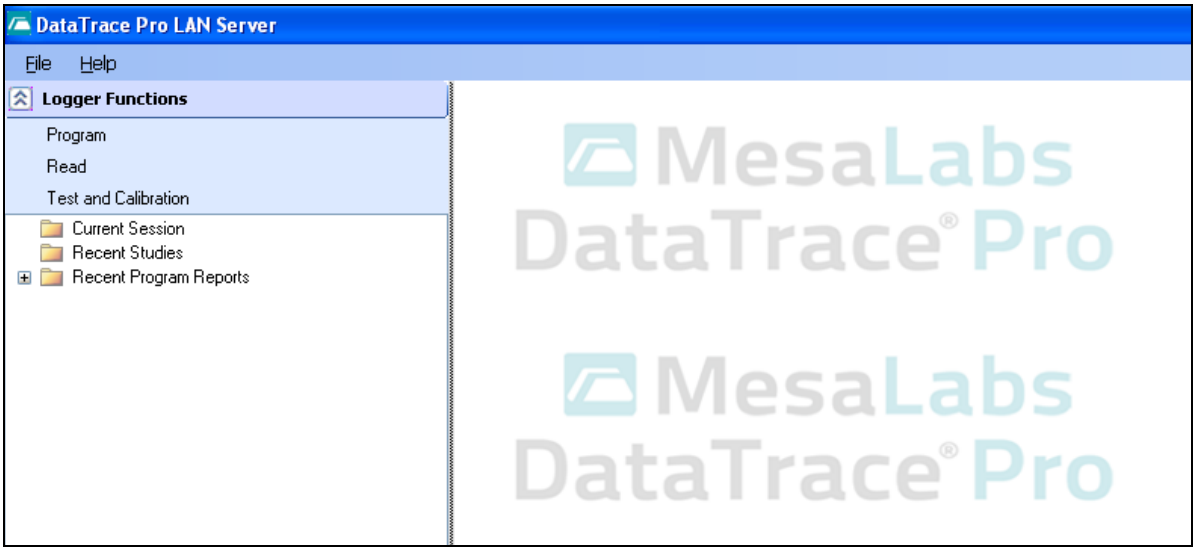
Right-click in the blank area of Configuration Tools category will show a pop-up menu with the following selections:

- Configure Device: Define Groups and Tags, set logging interval and other options
- Configure Alarms: Set alarm parameters for any wireless capable logger
- Enable Logging: Turn on wireless logging for a group or a single logger
- Disable Logging: Turn off wireless logging for a group or a single logger
- Groups: Create a new group
- Show Location/Tag: Use the location/tag information of a logger for display
- Show Serial Number: Use the serial number information of a logger for display
- Add New or Capture RF Device: Add new wireless monitors or smart repeaters
- Remove Device: Remove any unused or undergoing service devices
- Cal Verification: Access the calibration verification utility
- Set Host Channel: Change the transmit/receive channel of a host interface
- System Reports: For viewing/printing Setup, Security, Configuration and Alarms reports.

1.3.2 Logger Functions

In this category, you will find Program, Read, and Test functions that are applicable to MPIII and MP-RF loggers. Left clicking on Logger Functions label will expand to show the following items:

- Program: set logging start time, interval, radio options and channels, logging modes, study name and other options
- Read: download data from a logger, view the data, summary and graph
- Test and Calibration: perform quick tests and maintenance, access calibration and diagnostic utilities, upgrade logger firmware.
- Use Current Session, Recent items and the menu to instantly access study or programming reports



Right-click in the blank area of Logger Functions category will show a pop-up menu with the following selections:

- Display Study: Displays the selected study
- All Studies: Displays a list of all available studies
- Display Program Report: Displays the selected program report
- All Program Reports: Displays a list of all available program reports
- Cal Verification: Access the calibration verification utility

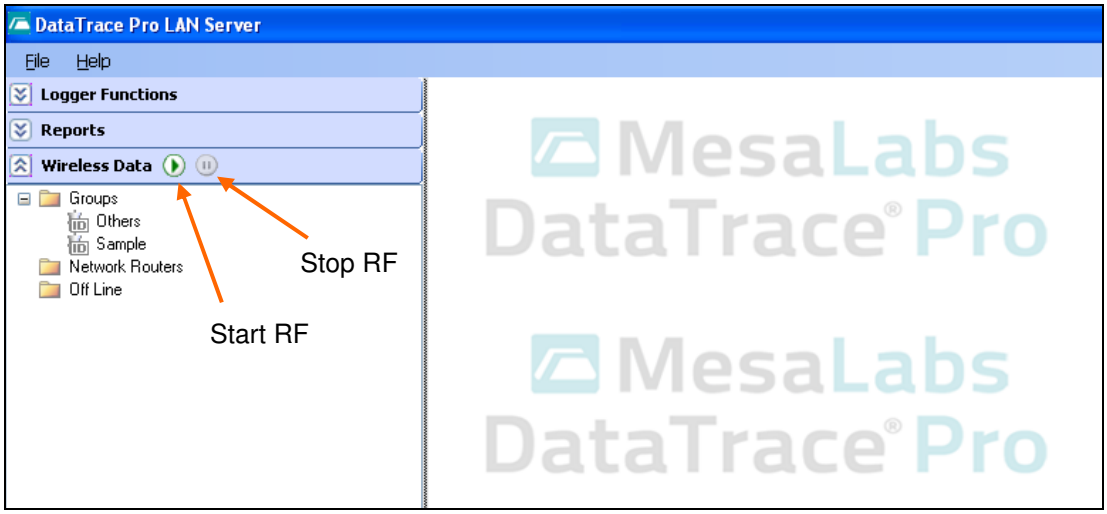
1.3.3 Wireless Data

This category is only available if you use active RF loggers in the DT Pro system. Left clicking on Wireless Data label will expand to show the following items:

- Start Button Enable the host radio receiver
- Stop Button Disable the host radio receiver

In Wireless Data category, you can perform the following actions:

- Use the pop-up menu to sort and select view styles
- Click on a Groups or the individual Logger to view real time data



Right-click in the blank area of Wireless Data category will show a pop-up menu with the following selections:

- Sort by Group: Organize the tree view display to show Groups
- Sort by Study: Organize the tree view display to show Studies
- Sort by Run ID: Organize the tree view display to show Run IDs
- Sort by RF Path: Organize the tree view display to show RF Path (used mainly in ENV systems).
- Show Location/Tag: Display loggers in tree view using their location/tag texts
- Show Serial Number: Display loggers in tree view using their serial numbers
- Use Off-Line Folder: Make visible or hide the "Off Line" folder. Off Line folder contains loggers that are not currently transmitting RF
- Cal Verification: Access the calibration verification utility

Wireless Data category offers the following features:

- Current data, alarm status and control, RF diagnostics and logger properties.
- Recent historical data display, both numerically or graphically
- Placement View

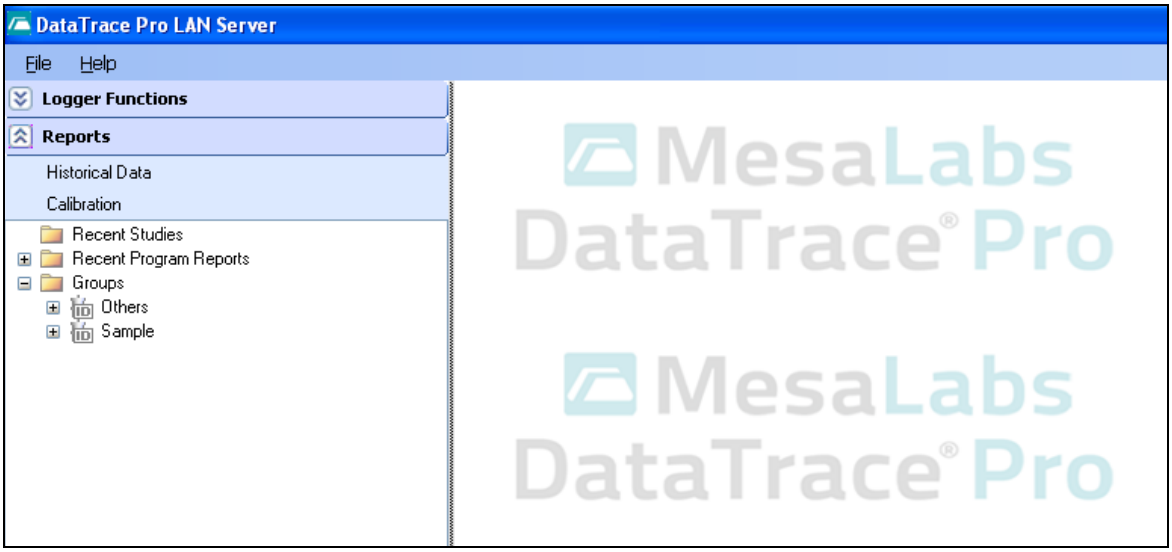
1.3.4 Reports

This category contains all features used in the data analysis, the creation and/or printing of reports. Left clicking on Reports label will expand to show the following items:

- Historical Data: Select and create reports from all available loggers and data
- Calibration: Access calibration reports

In Reports category, you can perform the following actions:

- Access defined data sets using the Recent Studies or Program reports
- Access data for a particular group or logger by selecting it and using the pop-up menu
- View data in a grid, summary or graph. Use the graph options for phase insertion and other data manipulations.
- Access Report Setup, select from standard report templates and create your own custom reports.



Right-click in the blank area of Reports category will show a pop-up menu with the following selections:

- Display: Click to display data of the selected logger or group of loggers
- Show Location/Tag: Display loggers in tree view using their location/tag texts
- Show Serial Number: Display loggers in tree view using their serial numbers

1.4 Help File

In DT Pro, there is a detailed Help file that can be accessed at any time. There are several ways to access the Help system in DT Pro:

- Click on Help, then select Contents or Tutorial
- Context sensitive – pressing F1 key on any window will bring up the Help file, displaying the topic for that window.

1.5 Support information

DT Pro only supports the following device models:

- MPIII
- MP-RF
- Network Repeaters

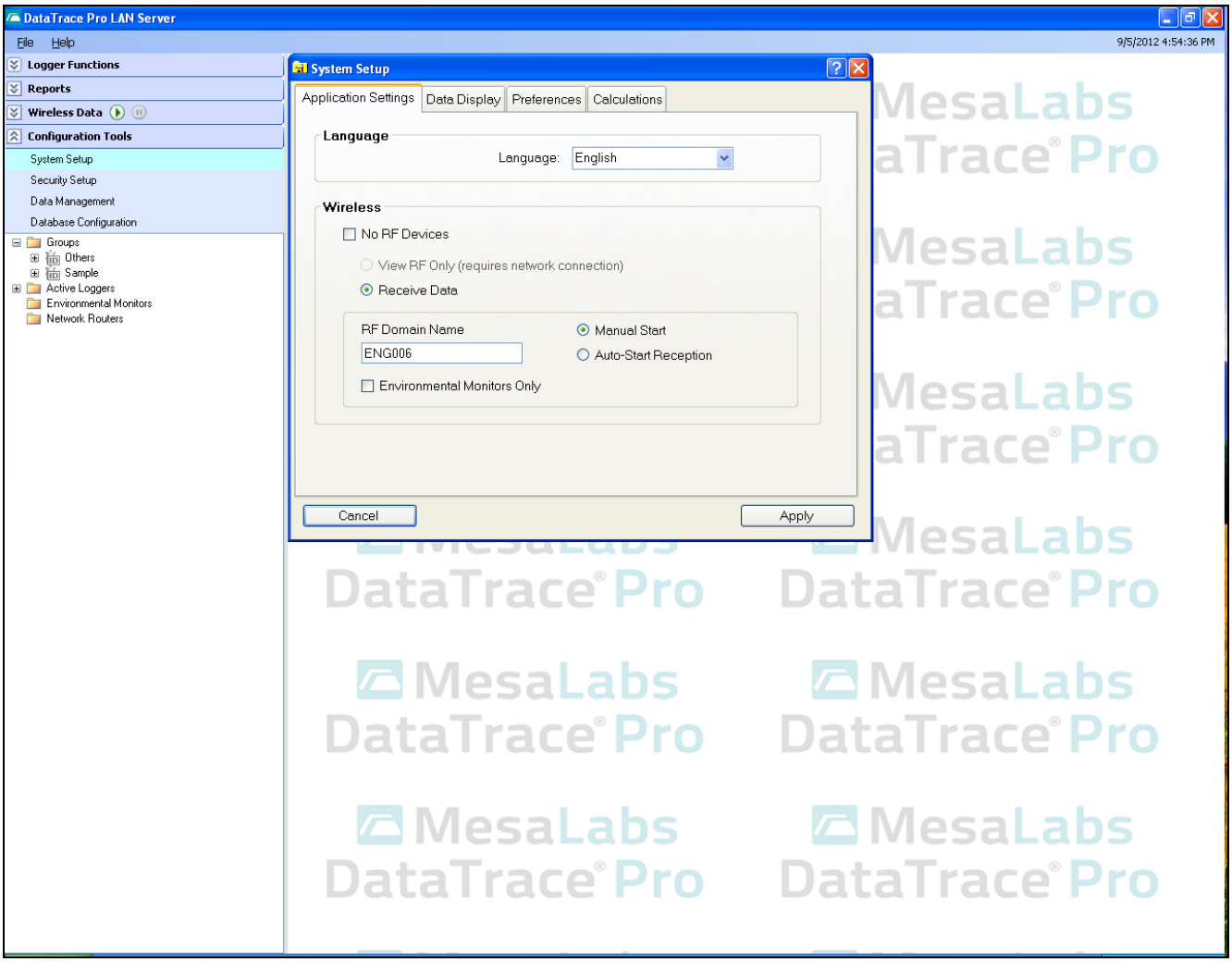
DT Pro no longer supports FRB loggers or mA loggers.

Chapter 2: System Setup

In this chapter, you will be able to learn in great details how to setup and configure DT Pro to fit your needs. To begin, left click on the Configuration Tools category, and then click on System Setup.

Note: Configuration Tools is accessible only for users with Admin or Power User permission levels, unless the system has been configured for "Windows Authentication" security mode.

The System Setup window below will appear:

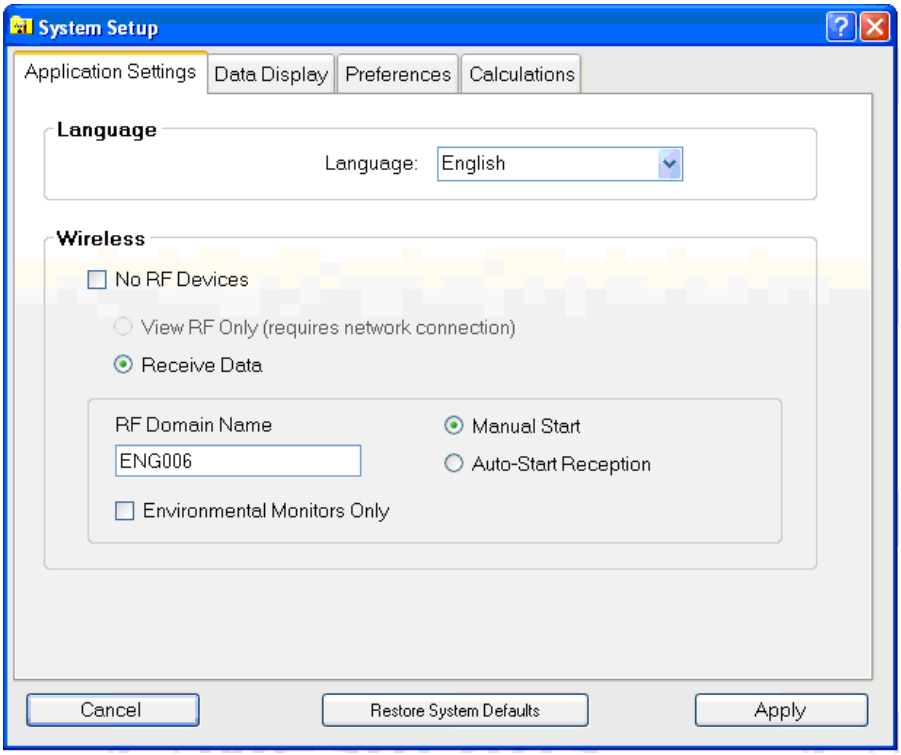


This window presents four tabs:

- Application Settings
- Data Display
- Preferences
- Calculations

2.1 Application Settings Tab

This is the default tab that is always visible when the System Setup window is launched. See below:



Language: Select the language you wish DT Pro to use for all windows display.

Wireless Settings: Configure the Radio features you wish to use.

- **No Wireless**: Select this if you will not be using any radio devices; options and features associated with radio functions will be hidden.
- **View RF only**: Select this if Radio data is being received by another remote computer / DT Pro database.
- **Receive Data**: Select this if there is (or will be) a Host RF receiver connected to your computer and you will be receiving RF data with it.
- **Auto-Start Reception / Manual Start**: If Auto-start is selected, radio reception will begin automatically when DT Pro is started (error messages will be generated if there is no Host receiver connected at start up).
- **Environmental Monitors Only**: Select this if no IR interface capable loggers will be used. Logger Functions will be hidden.

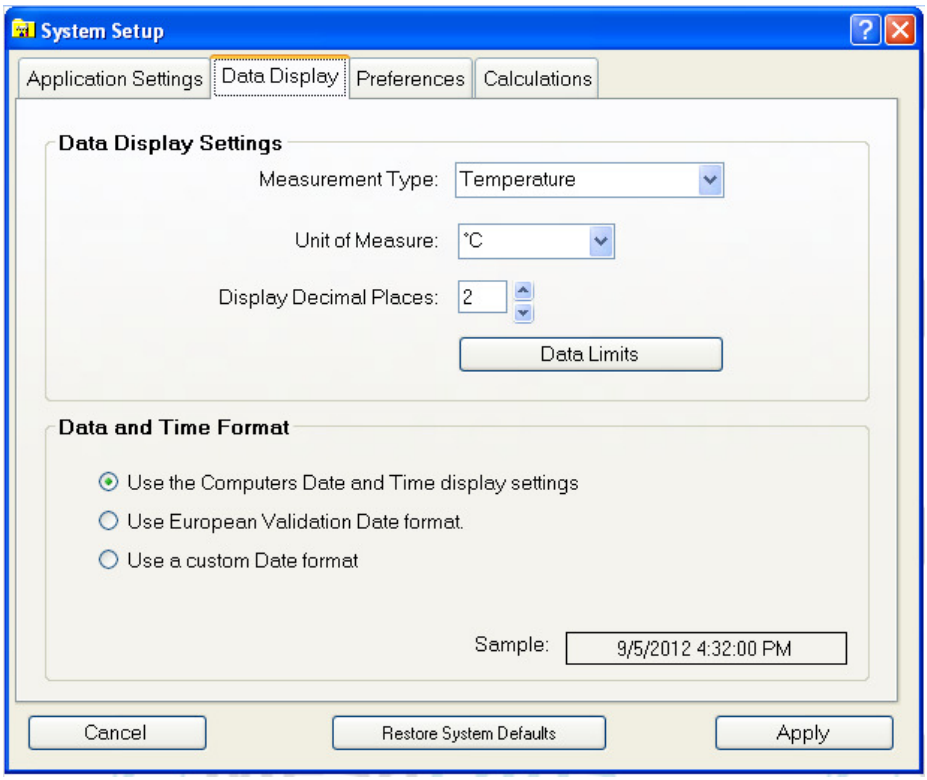
RF Domain Name: The domain name is used to generate an encrypted control key which is loaded in RF capable devices (when loggers are programmed, when environmental monitors or repeaters are captured, or when RF host interfaces are started). RF control functions and data reception can occur only when the domain control key matches the system, even if RF transmissions occur on the same RF channel. If it is desired to program 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.*

The available options will change depending on existing or prior selections. Wireless data reception is available only in the DT Pro Plus or LAN Server editions.

If you will be using the radio functions, you will need a MPRF Host radio receiver. This is a USB device which requires the installation of USB drivers for proper operation. See USB PC Interface Installation in the Help File for further information.

2.2 Data Display Tab

Use this tab to configure how the data points are displayed on the screen, or on reports. Clicking the Data Display tab will show the following:



Data Display Settings
For each type of measurement, select a unit of measure and the number of decimal points to display or print.

Contact Mesa Labs if you wish to use a unit of measure that is not available. Some units can be added without requiring new or upgraded software.

The "time" unit selection is used in Reports for time based statistics or Pass / Fail evaluations.

Date and Time Format
Select how you want date and time to be displayed and printed.
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).

Data Limits
Access to advanced 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. *Note: these settings replace the Crop RH 0 to 100% option available in DT Pro version 1.1.*

2.2.1 Data Limits, Exception and Data Deletion options

The data limits, exception handling and data deletion options screen is accessed from the System Setup window in the Display tab. Access to these settings is limited to system administrators only.

Changes to these settings are saved only when the Apply button is clicked.

All changes to these settings will be recorded in the audit trail.

Data Limits

The data limits settings are used to trap measurements that are obviously erroneous. Bad measurements may occur due to logger malfunction, process upset, conditions beyond the calibrated range of the logger, or use of the logger beyond its specified capabilities (e.g. using an RH logger in a condensing environment which causes the RH sensor to get wet).

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

- Maximum: The highest value that will ever be displayed for the data type.
- Minimum: The lowest value that will ever be displayed for the data type
- Use Rate of Change limits: This option is not available for the standard exception handling mode (see below). If enabled, the difference between sequential data points will be evaluated and compared to the ROC (rate of change) limit. The evaluation is dependant on the ROC units selection and may be either independent of logging interval (per logged reading) or defined relative to rate of change per minute or per second.

Note: For RH measurements, the RH limits replace the "Crop RH 0 to 100" option of DT Pro version 1.0. To replicate this functionality, set the RH minimum to 0 and RH Maximum to 100.

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.

- Save data, crop displayed data to max. or min. settings (standard default). Data that exceeds the 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 evaluation is not supported when this mode is used.
- Discard (mark as undesired) out of range data point(s). Data that exceeds the limits will be saved but will be marked such that, under normal circumstances it will not be seen nor 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.
- Discard first out of range data point and all subsequent data. Similar to previous option; when reading a logger, both data that exceeds the limits and all subsequent data points will be marked as undesired. If the data is being received via RF, all subsequent data will also be marked until the logger is programmed again (the Configuration Tools, Device configuration window may be used to re-enable standard RF reception).

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); however, if the displayed value is to be cropped to a minimum or maximum value, the current settings are used.

Data Deletion Handling

These settings determine whether it is permissible to delete data from the database directly from the Reports view Graph or grid. Data deletion is always allowed for database maintenance purposes by using the Configuration Tools>Data Management utility. The options are:

- Allow data deletion from Reports view (standard default).
- Prohibit data deletion from Reports view.

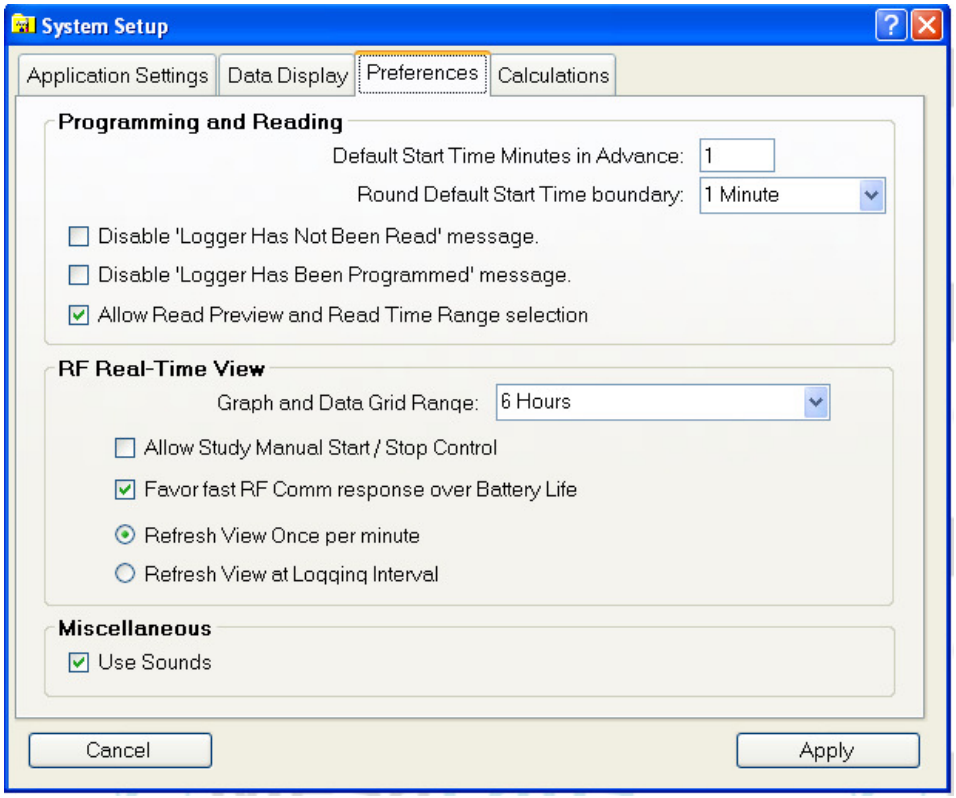
When data is manually deleted or marked as undesired, a confirmation message with option to enter a comment or explanation for the action will appear. The action, logger serial number and data range, the comment (if any) will be recorded in the audit trail.

If data deletion is allowed, it is available only to system administrators. Marking data as undesired is available to both administrators and power users.

Notice regarding 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 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.

2.3 Preferences Tab

Use this tab to configure system settings to fit your needs. Clicking this tab will show:



Programming and Reading

- **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).
- **Default Start Time Boundary**: Sets whether the start time should be rounded to a whole minute, a whole hour or some intermediate time.
- **Disable "Logger has not been Read" message**: Disables the generation of a warning message when programming a logger that has not had is current data downloaded.
- **Disable "Logger has been Programmed" message**: Disables the message indicating programming success.
- **Allow Read Preview and Read Time Range selection:** When downloading data from a logger, allows the user to specify a specific date and time range for the data. See Chapter 7: Reading Loggers for details.

RF Real-Time View

- **Graph and Data Grid range**: Items in the real time view window shows both current and historical data. This setting defines how far back the historical data should go.

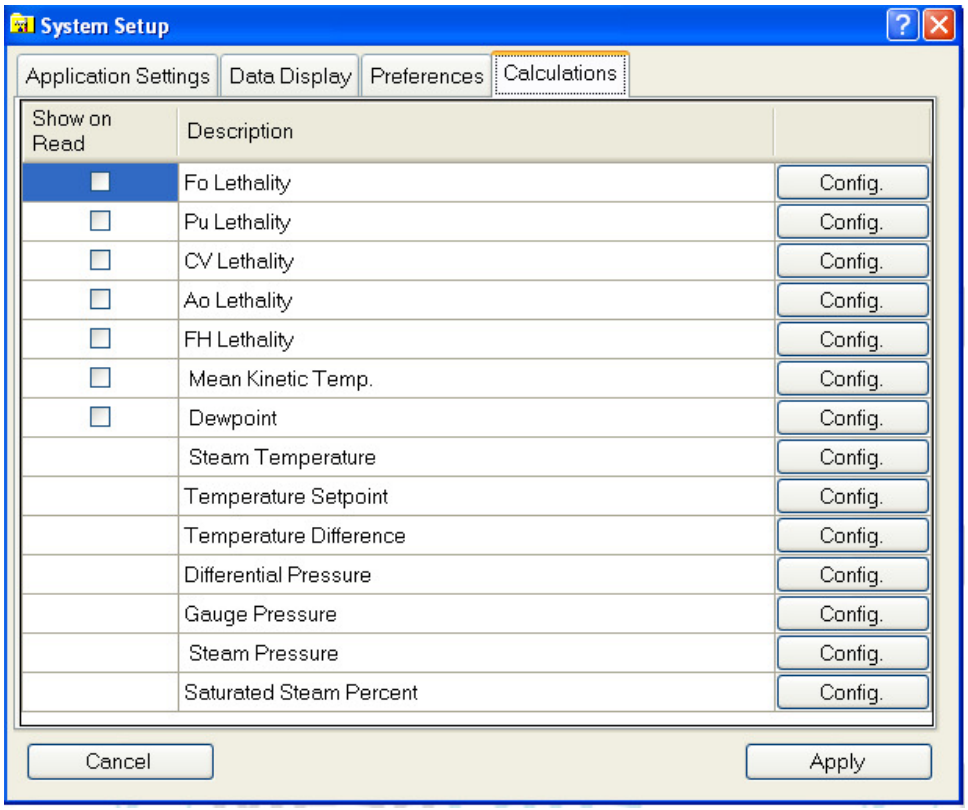
- **Allow Study Manual Start / Stop control:** If selected, controls will be visible in the real time view window for the user may assign study names and manually control when a study starts or stops.
- **Favor fast RF comm response over Battery Life:** This option allows loggers to re-transmit data multiple times when a bad radio link is detected. This can improve instantaneous communications reliability, but the batteries might be depleted faster than normal. The additional depletion rate is dependant on many things, including logging interval and the necessity for re-transmissions, but would be expected to not shorten battery life by more than 20 - 30 %. Note that if not used, all loggers re-transmit at least once, and there are other mechanisms in place to retrieve missed RF data. This option has no effect for loggers with older firmware revisions.
- **Refresh View (Once per minute / at Logging interval)**: Data in the real time view will be refreshed per the selection (applies to remote data viewing only, data received on a locally connected RF Host is always displayed instantly).

Miscellaneous

- **Use Sounds:** Sounds will be generated to indicate the success or failure of programming, reading and testing operations (the computer must have speakers for sound generation).

2.4 Calculations Tab

Use this tab to configure calculation settings to fit your needs. Clicking this tab will show:



- All available calculations are shown on the grid.
- **Show on Read**: Check this box if it is desired that a calculation value be generated when data is downloaded form a logger (in the Read window).
- **"Config." button**: Access / set various calculation parameters.
- 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). Certain types of calculation may be added to this library without affecting the performance of DT Pro. Upgrades containing new calculations may become available, and Mesa Labs will entertain requests for the addition of calculations.

2.4.1 Available Calculations

Notice: Unlike DTW or DTRF, the appearance of a calculated value on a report is not defined at the system setup level. Different report templates may be defined which use different calculations. Multiple calculations are allowed for any report.

Once a calculation has been selected for a report, it will by default be performed for all loggers of the required data type. If it is desired that the calculation not be performed for one or more loggers, the calculation may be individually disabled in the data grid view. Select a column of logger data and right click to expose the grid menu. Calculations that are defined for this logger are shown, and may be checked or un-checked to enable or disable the calculation for that specific logger.

Lethality

Lethality is a calculation which quantifies the efficacy of a sterilization, pasteurization or similar process.
Five lethality calculations are provided, each may be configured independently.

The lethality algorithm takes the form:

$$Lethality = \sum_{1}^{N\_Minutes} Z^{(Measured\_Tempearture - TX)/Z}$$

- The values of TX, Z and Threshold must be configured. There is no facility to set or restore "typical" values. *See also Typical Lethality Parameters in DT Pro Help File.*
- The user may edit the units (name) of the Lethality calculation (typically, Fo, Pu, CV or Ao), and may add new units if desired.
- The standard time base is 1 minute; a 1 second optional time base (for Ao) is available.
- The user may define a comment for the calculation. This comment can optionally be printed on those reports that use the calculation.
- The user may set whether the calculation produces a columnar output or only the final value.
- The user may set whether the results are summarized (e.g. a summary printout may include minimum and maximum Fo for a group of loggers).

Notes:

- *It is recommended that the TX, Z and threshold settings be included in the calculation comment so that these may appear on a printed report.*
- *Several Fo (or other) calculations with different parameters but the same unit of measure can be defined and subsequently used on different reports.*
- *Language translation is not available for Lethality units. If it is desired that CV be translated as VC, the user should edit the lethality calculation unit according to his or her language preference.*

Mean Kinetic Temperature (MKT)

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

Dewpoint

Dewpoint is a value expressed in temperature units and calculated from logged relative humidity and temperature. No configuration parameters are required. Options are given to replace RH % or show both RH % and the calculated Dewpoint. Dewpoint is displayed in the selected units of measure for temperature display (e.g. °C or °F).

Steam Temperature

Stem Temperature is a value expressed in temperature units that is calculated from logged pressure. No configuration parameters are required (other than summary or comment). Steam Temperature is displayed in the selected units of measure for temperature display (e.g. ℃ or ℉). The algorithm used to calculate steam temperature is per ISO 17665-1:2006 6.1.2b.

The following items were added in DTCalc.dll version 1.1

Temperature Set Point

Allows the user to configure a temperature set point. The result of the calculation is the difference between the measured temperatures and this set point.

Temperature Difference

Allows the user to define a reference temperature logger. The difference between this logger and all other temperature loggers will be calculated. To define a reference logger; select its column of data in the data grid and right click to expose the data grid menu. Click the Reference menu item to select (or un-select) the logger. No calculation results will be produced until a reference has been defined.

Differential Pressure

Allows the user to define two pressure loggers. The difference between these loggers will be calculated. Select pressure loggers by column in the data grid and right click to expose the data grid menu. Click the Reference menu item to select (or un-select) each pressure logger. No calculation results will be produced until two pressure loggers have been selected. Only one differential pressure calculation (using two loggers) is supported per data set.

Gauge Pressure

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

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.

Saturated Steam Percent

Allows the user to define a reference temperature logger from which a steam pressure will be calculated; Logged pressure will be evaluated as a percentage of this theoretical pressure. In configuration, a temperature limit may be set (no calculation will be performed if the temperature is lower that the limit). An upper percentage limit may also be defined (in order to limit the calculation in the instance of a non saturated steam environment).

2.5 System Setup Report

A printout of Setup parameters can be obtained from the System Configuration Reports. The report provides details on the local computer installation and setup, Wireless radio settings and user preferences like data units of measure. Also includes all calculations parameters (e.g. Lethality settings). To get this report, with Configuration Tools as the currently selected category, click anywhere in the blank area of Configuration Tools, then select System Reports, then click on Setup… This will bring up the preview window where you can then preview the Workstation Setup Report.

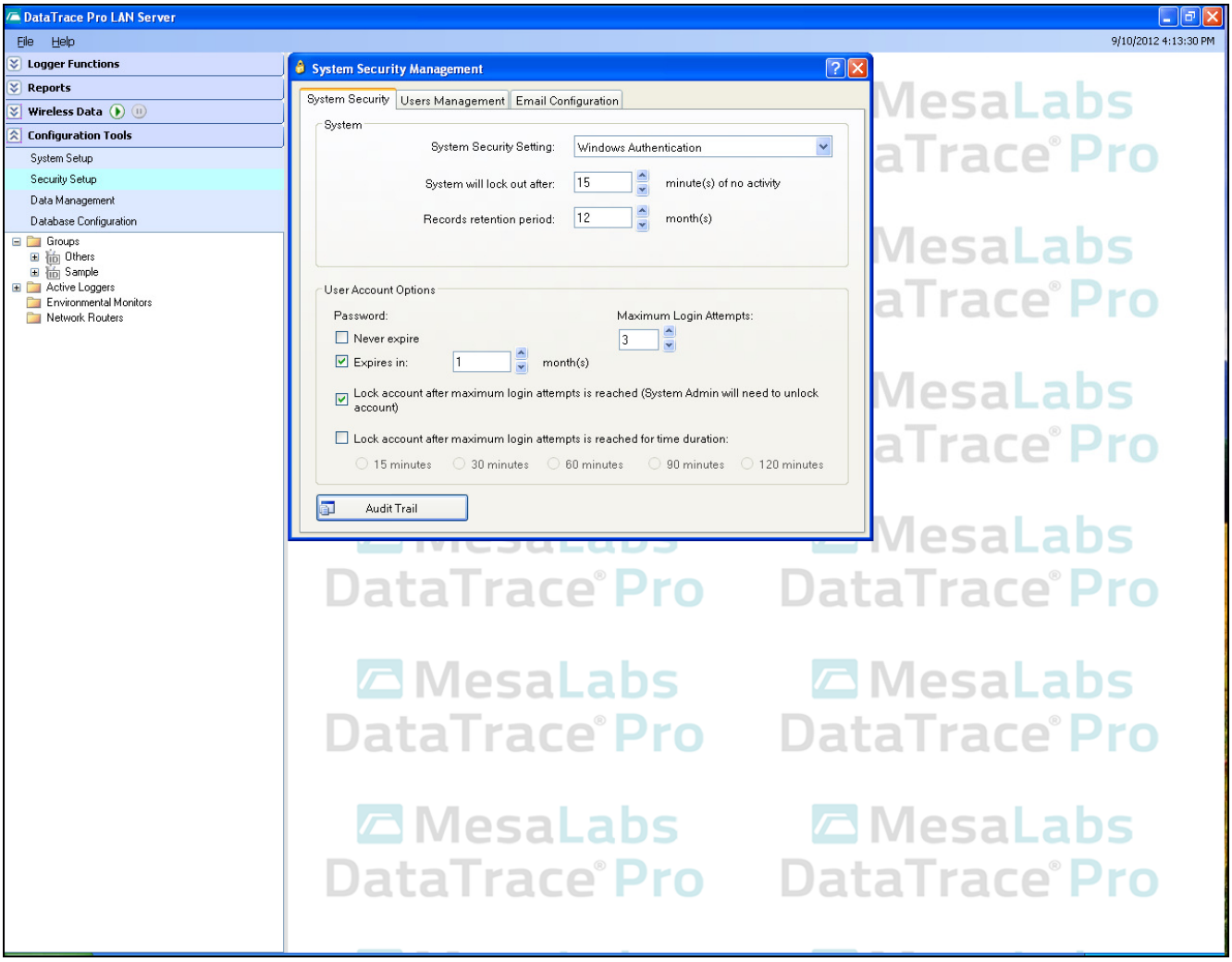
Chapter 3: System Security

In this chapter, you will learn how to configure system security settings, and perform user management tasks.

Notes:

1. *Security Configuration is accessible only to the system administrator (Admin permission level), unless the system has been configured for "Windows Authentication" security mode.*
2. *Access to the Security settings is not available while RF data reception is active.*

To access the System Security Management window, expand **Configuration Tools** and select **Security Setup**. The System Security Management window below appears:

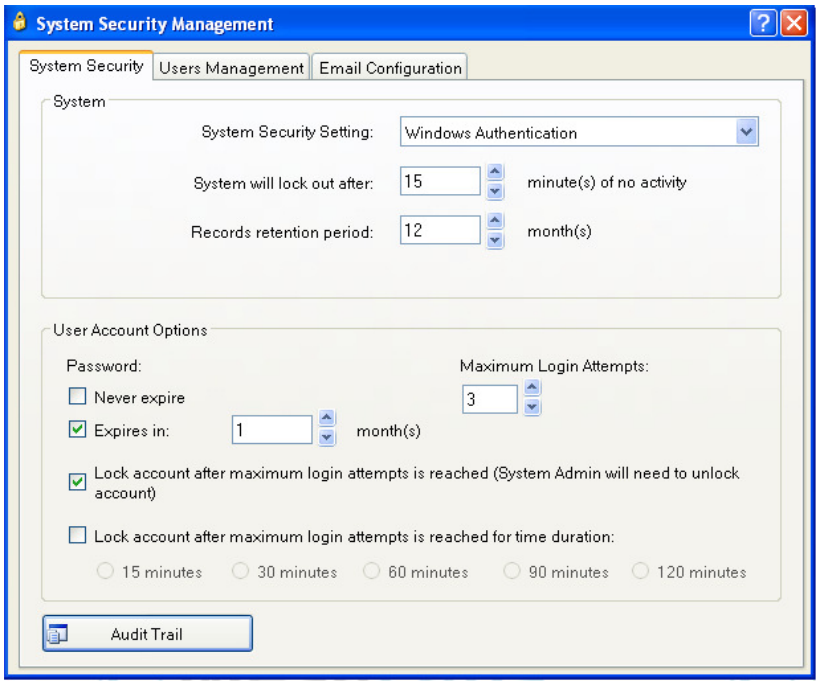


The System Security Management window has three tabs:

- System Security
- Users Management
- Email Configuration

3.1 System Security Tab

This is the default tab that will always appear when the System Security Management window is launched. Below is a screenshot of the tab in greater details:



3.1.1 System Security Setting:

The level of Data Security used by DataTrace Pro is established by the Security setting. The security settings is normally established at the time of DT Pro first use, but may be changed at a later date. The available settings are:

- **Windows Authentication:** Low level security. Relies on the Windows login system; no addition login is required. Allows the user or users to access all functions of the program without restriction. Cryptographic records are maintained but checks are bypassed during execution of the program to increase speed. An audit trail log is maintained. Many users will find this level appropriate for their activities if a higher level is not a regulatory requirement.
- **DT Pro Authentication:** Medium level security. In addition to Windows Authentication mode, requires that the user login in order to access the program. Each user is assigned a permission level. System will lock after the defined inactivity time. The authorization level allows access only to those function levels of the program that the user has been approved for.
- **Regulatory Compliant:** Highest security level. Complies with US FDA's 21 CFR Part 11. In addition to the "Medium" security features, cryptographic checks are enabled for the detection of data tampering, and "Electronic Signatures" are required for any user initiated data acquisition, process modification, calibration or other activities as stipulated by the regulation. This mode is not available in the DT Pro Basic or Standard editions.

Note: The act of using the Regulatory Compliant mode does not in and of itself assure compliance with US FDA's 21 CFR Part 11; additional details below.

3.1.2 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). This setting does not apply to Windows Authentication mode. A 15 minute maximum is allowed for Regulatory Compliance (90 minute maximum for DT Pro Authentication). *A locked system will continue to receive radio data!*

3.1.3 Active record retention period:

When data is archived (using Configuration Tools > Data Management), a copy of the data, studies, alarms et. al. 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 may be subsequently accessed using the Data Management tool.

Note: This setting may be distinct from any company policies pertaining to record or data retention. Those policies should be applied to the archive files. This setting is intended to define a time frame for simplified data access, or report generation. Periodic archiving of data will improve overall database performance.

3.1.4 Strict Digital Signatures (All):

This option is only available when the Regulatory Compliant mode is used. One interpretation of US FDA's 21 CFR Part 11 is that the results of a valid user login, with confirmed continuous use, may be used to digitally sign records. Use of this option implements a stricter interpretation: the user will be asked for a digital signature (confirm his 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 loggers, accessing security, defining or acknowledging alarms; and in all cases, record modifications are tracked in the audit trail (with either the signatory or the authenticated logged in user name).

3.1.5 User Account Options:

These settings control when and how Passwords expire, and what happens on failed login attempts. The controls are self-explanatory.

Password Requirements

The minimum requirements for password validity are:

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

Note: To achieve regulatory compliance, users should also follow their own company policies for password creation.

3.1.6 Audit Trail:

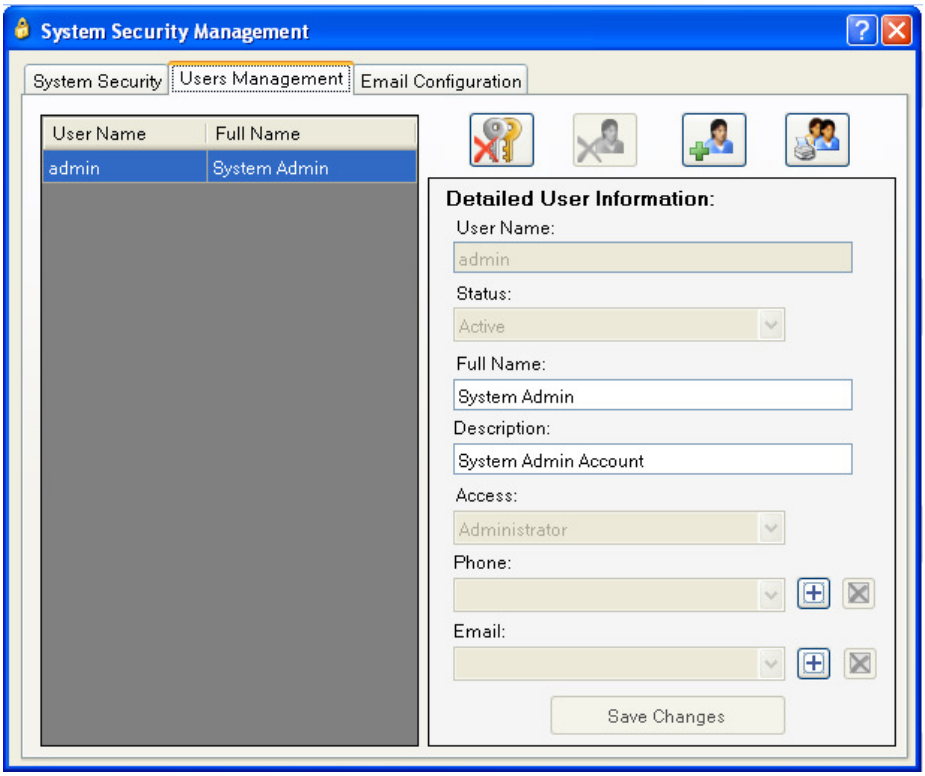
System Auditing occurs in all security modes. This Audit Trail function generates and maintains log of certain system events and user activities. The audit trail may be viewed by clicking the Audit Trail button. Printouts may be obtained using various viewing and sorting options.

Note: When a medium or high security level has been selected, the user can manually lock the system by clicking the Lock icon. Attempting to access a locked system will raise the Login dialog screen.

3.2 Users Management Tab

This is the second tab of the System Security Management window. In this tab, you can perform users management tasks such as creating a new user, disabling (or lock) an existing user account, delete an existing user account, etc.

Clicking this tab will display the following:



On a new DT Pro installation, by default, the system is shipped with an "admin" user account. This is the main System Admin user account for DT Pro. To log in for the very first time, use the following information:

User name: admin
Password: admin

All defined user accounts are displayed in the grid on the left side of the tab. If a user account is selected, the details of the account are shown on the right side. The four buttons on the top, from left to right are:

- **Delete (Reset) User Password**: The user password (after confirmation) will reset to match user name. Used in the event a user forgets his password.
- **Delete User**: The user account (after confirmation) will be permanently removed
- **Add New User**: Creates a new blank account. All required entries (denoted by a red check mark) must be made before the new account can be saved.
- **Print Users**: Creates a report of the selected user account, or optionally, of all users. If all users are selected, the report also includes all other security settings.

Notes:

- *When a user logs in and user name and password are identical, 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-mail addresses) for use by the alarms system.*

On the right side of the tab, the details of the selected user account are shown. Each user account has the following:

- **User Name:** The system identifier for the account and for user Login.
- **Status**: Whether the account is locked or not (active or disabled). The administrator may lock or unlock accounts as necessary.
- **Full Name:** The full name of the user. May optionally appear on reports.
- **Description:** A reference field for use by the administrator.
- **Telephone:** The telephone number of the user. This information is not used in the current release of DT Pro.

- **E-mail:** One or more e-mail addresses for the user. Used by the alarms system when a user contact has been defined. (Only supported in Windows XP)
- **Access:** The permission level assigned to the account.

Notes:

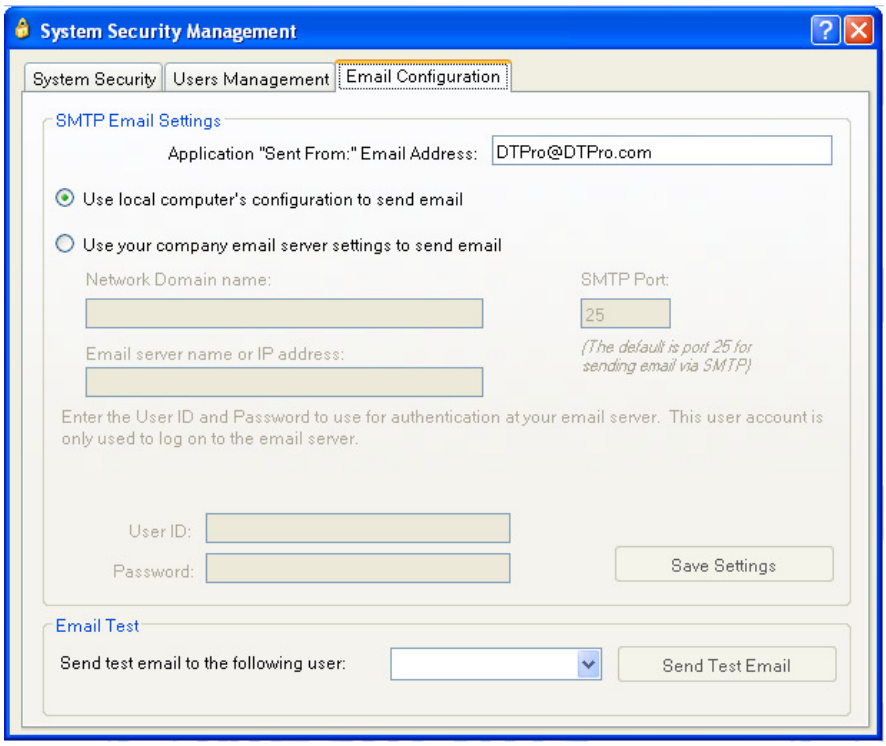
- *When creating a new user account, the mandatory fields are the ones with the red "x" to the right of that field. Once all of the mandatory fields are filled in, the Save Changes button will be enabled to allow applying the changes to the database, or allowing the user account to be created.*

Permission Level Description:

- **Administrator**: Access to all DT Pro functions and features.
- **Power User**: Access to all DT Pro functions and features except Security Configuration
- **Standard User**: Access granted to standard DT Pro functions and features. Access (and visibility) to Configuration Tools and Report template modification or creation is denied.

3.3 Email Configuration Tab

This is the third and last tab of the System Security Management window. Clicking this tab will show details on how to setup SMTP (Simple Mail Transfer Protocol) Email Settings, as shown below:



SMTP E-mail Settings: Enter a "Sent From" address that will be used for all e-mails generated by DT Pro. There are two main options for how e-mail is sent:

Use Local Computer's Configuration: Simplest to use. If selected, all other options will be disabled (are not required). Will not send an e-mail through a fire-wall, but can send an e-mail internally.

Use Company Email Server Settings: Required to send an e-mail through a fire-wall. The required information should be readily available from IT personnel. **WARNING:** If the password has expired or changed for the User ID used to authenticate, you must enter the new password and save the changes. DT Pro alarm e-mail will not function with an expired password! If allowed and/or possible, it is

preferable to create a "dummy" network user account restricted to e-mail use only, with a no password expiration option.

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

Notes:

- *In order to be able to set up the email feature in DT Pro, the PC must have SMTP Service for Windows installed. SMTP Service for Windows is normally available as a component of Internet Information Services (IIS) for Windows. Please consult your IT personnel for assistance in enabling this option in Windows.*

3.4 US FDA 21 CFR Part 11 Compliance:

Using DataTrace Pro software with the Regulatory Compliant mode enabled is not an assurance of USFDA 21 CFR Part 11 compliance. In order to comply with this statue, other requirements may be (but not limited to):

- Documented procedures for how the DataTrace hardware and software are used.
- Documented procedures that define security policies, password usage and quality procedures
- Documented personnel training records.
- Documented validation of DataTrace Pro software installation, configuration and functionality.
- Documented procedures for data security, archiving, database back-up and disaster recovery.

Mesa Laboratories, Inc. can provide assistance with these issues. A formal DataTrace Pro Software Validation package is available for purchase. On site validation assistance or execution is available in some areas.

3.5 Data Security

All data and configuration information is stored in the DT Pro SQL database. The various elements of the database are password protected so as to limit or bar access to those with advanced SQL tools. 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 pertaining 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 US FDA 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. These advanced settings should conform to documented data handling procedures.

Chapter 4: Device and Alarm Configuration

In this chapter, you will learn how to configure devices in the DT Pro system so that they will be properly managed by the DT Pro software.

4.1 Managing Groups and Tags

DT Pro treats each measurement as a unique entity. Each measurement or channel from devices with more than one channel (e.g. a pressure / temperature logger) is treated separately.

DT Pro allows the user to assign a **Tag** or location identifier to any measurement (a device channel). This Tag might represent a location, a test equipment number, or some other identifier of convenience. Additionally, the user may organize loggers or monitors into logical **groups**, and assign any desired name to the group. If desired, the DT Pro reporting tools allows the user to generate summaries or graphs by group (in Report Setup > Report Manager > Advanced Preferences).

In the pop-up menus of the various browser views, the user may select whether to display loggers using their serial number or their assigned Tag ID; Report templates can be created in which loggers are identified by either serial number or tag, with options to associate both on a cover page printout. The browser view can be sorted by group (and other ways). Real time radio and report data can be viewed by selecting a group. Using the group and tag feature allows for both efficient data access and customized reporting.

Notes:

- *Configuration Tools is accessible only for users with Admin or Power User permission levels (unless the system has been configured for "Windows Authentication" security mode).*
- *A printout of existing devices and configuration settings can be obtained from the System Configuration Reports.*

4.1.1 Setting Groups and Tags

Create a new group:

To add a new group, do the following:

- Click to expand Configuration Tools category
- Click on the Groups folder in the tree view display and right click to bring up the options menu.
- A new group may be added from this menu by clicking Add New

Delete an existing group:

To delete an existing group, the group has to be an empty group, i.e. no devices assigned to the group. Follow the steps below to delete a group:

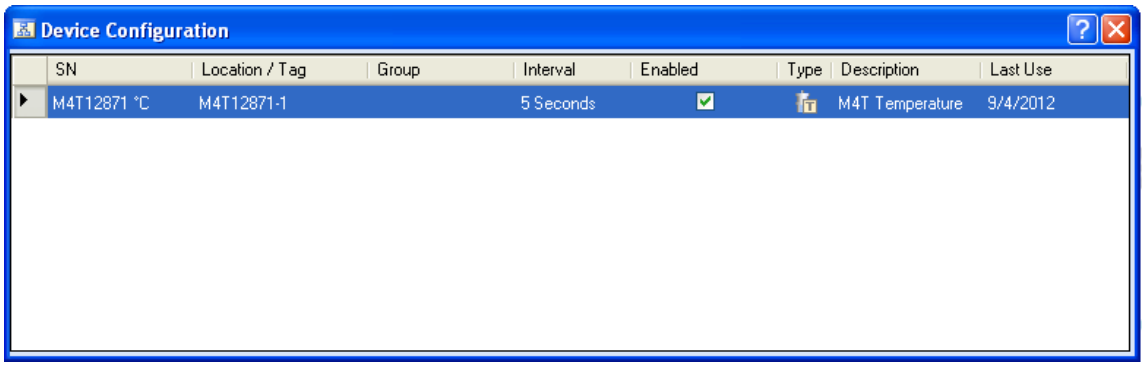
- Click to expand Configuration Tools category
- Click on the group name of interest that you want to delete. Make sure that it does not have any devices assigned to it. The simplest way to tell if there are still devices assigned to the selected group is to see if there is a “+” to the left of the group name. If there isn’t one, then the group is an empty group, and you can then proceed to delete the group.
- Right click on the selected group to bring up the options menu.
- Select Groups, and then select Remove option.
- The selected group name will now be deleted.

Assign a device to an existing group:

A device, initially, will show up under the “Others” group name. This means that this device has not been assigned to any group yet. To assign a device (logger or monitor) to an existing group do the following:

- Click to expand Configuration Tools category
- Click the “+” to the left of the “Others” group name to expand it.
- Select the device of interest

- Right-click on the device of interest and select Configure Device from the menu
- The Device Configuration window will show the current (or default) Tag and group for the selected device, as shown below:



- The Tag may be edited directly in the Location/Tag column cell for the device.
- Click on the Group column cell, from the menu that appears, select a group from the available groups or create a new group if desired.

4.1.2 Other Device Configuration Options

From the screenshot above, there are other Device Configuration options that have not yet been discussed. These are: Interval, Enabled, and Description.

Interval: The data logging interval setting may be changed for monitors and RF Capable loggers. **Warning**: Changing a logger's interval dynamically (using this method as opposed to programming the logger) may result in data loss. If the logger was programmed using the "**Never Stop**" mode (see Chapter 5: Programming Loggers), the logger is operating identical to an environmental monitor, and changing interval dynamically will not cause problems. If however, the logger was programmed using "**Stop When Full**", changing the interval dynamically will also **reset the logger start time;** it will be the time the command was received rounded up to whole minutes. If data is subsequently downloaded from the logger, data will start at this new time, not at the original programmed time.

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

Description: User may enter any descriptive information such as tolerances or calibration due information. This description can optionally be included in a report.

4.2 Configuring Repeaters

A DataTrace Repeater is a device that can receive a transmission and re-transmit it in order to extend communications range. This functionality requires AC power for nominal performance.

Note:

- *The user must have Admin or Power User permission levels in order to execute these procedures.*

4.2.1 Start up Procedure

The following is required for new Environmental Monitors or Smart Repeaters / Routers

1. On the repeater, turn power OFF.

2. Enable Radio Reception on the desired Channel *(on Wireless Data, click the green "Start" button, see Chapter 6: Receiving and Viewing Radio Data for details)*
3. Expand **Configuration Tools**, select the Monitors or Routers folder, and right click within the browser view to bring up the menu
4. Select "**Add New or Capture RF Device**". Enter the Serial Number of the repeater when prompted.
5. Place the repeater close to the RF host receiver (5 to 30 feet).
6. Plug in, turn on or place battery into the repeater to power it up.
7. The repeater will scan all channels looking for a receiver. Verify it appears within the Wireless Data browser view.

Note: This procedure requires that RF reception be enabled prior to powering up the repeater so as to prepare the Host receiver 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 prior attempting again.

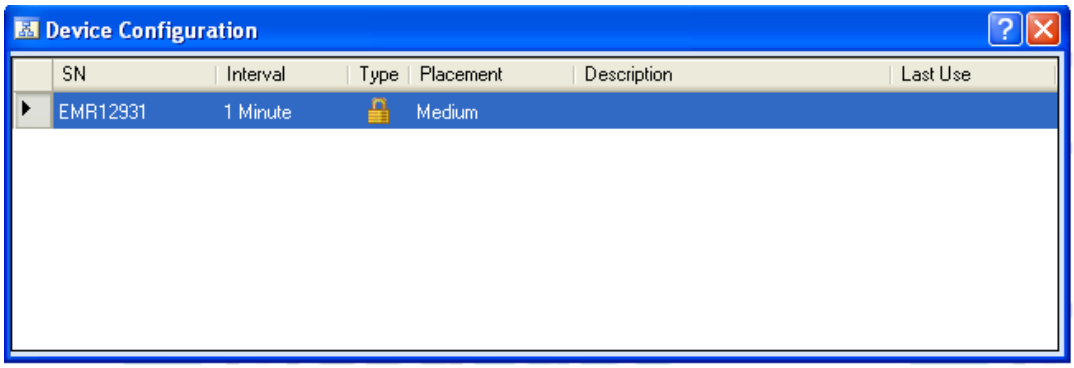
This procedure sets and locks the RF channel for the device and establishes the current computer as the RF destination. To change the RF channel or use the device on a different computer, re-execute this procedure with the Host set to the desired channel.

This procedure need only be exercised one time (as long as the device is used on the same computer and RF channel), even if the device is powered off.

If the device is already in the system, but had been out of use, but is configured for a different RF channel, or a different computer, starting with the device powered down, perform this procedure. For ease, after opening the appropriate Monitors or Routers folder, select the Serial Number of the device prior to clicking "Add New or Capture RF Device" so that the serial number input screen will be pre-populated.

4.2.2 Configuration

1. Expand **Configuration Tools.**
2. In the browser view, find the repeater and select it (click on it).
3. Right click to bring up the options menu, select **Configure Device.** The Device Configuration window below appears:



4. Click on the **Placement** column, from the menu that appears, set whether the repeater will be near the host, a medium distance or far from the host. (Near is within 150 feet, medium 150' to 300', far is 300' or more, see below for details).
5. Click on the **Interval** column, from the menu that appears, 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 logging interval determines how often the repeater will communicate with the host receiver for status checks and time synchronization.

4.2.3 Details

- **Placement:** The placement setting is used by the mesh network system to efficiently route data toward the host receiver; 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 not have more than 4 routers set as Near and not more than 6 to 8 as Medium, all others should be set to Far (even if they are close to the host); these will then generally not participate in data relaying unless it is needed.

- **Interval**: The interval setting may be changed at any time, and may also be changed for loggers. **Warning**: Changing a logger's interval dynamically (using this method as opposed to programming the logger) may result in data loss. If the logger was programmed using the "**Never Stop**" mode (see Chapter 5: Programming Loggers), the logger is operating identical to an environmental monitor, and changing interval dynamically will not cause problems. If however, the logger was programmed using "**Stop When Full**", changing the interval dynamically will also **reset the logger start time** (it will be the time the command was received rounded up to whole minutes). If data is subsequently downloaded from the logger, it will start at this new time, not at the original programmed time.

4.3 Configuring Device Alarms

The DT Pro alarm functions are applicable only to radio devices. As data is received via radio, they are evaluated per defined alarm conditions. Historical or download data is not evaluated. If an alarm is generated, the result is displayed via icons, and may optionally result in an e-mail or other type notification.

Notes:

- *Configuration Tools is accessible only for users with Admin or Power User permission levels (unless the system has been configured for "Windows Authentication" security mode).*
- *Alarm functions are available only in the DT Pro Standard, Plus or LAN Server editions.*

4.3.1 Accessing Alarms Configuration

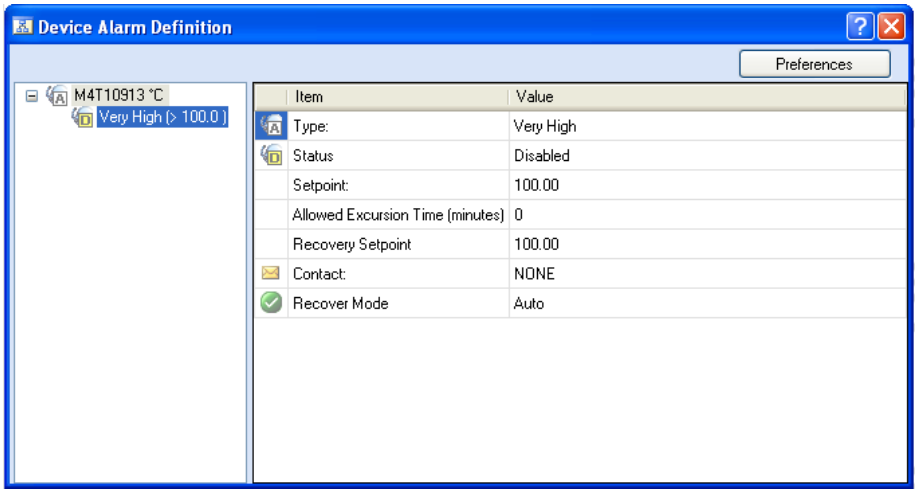
To access the Device Alarm Definition window, do the following:

1. Expand **Configuration Tools**
2. In the browser view, select a group or logger for which alarms are to be defined
3. Right click to bring up the options menu, choose **Configure Alarms**.

4.3.2 Defining Alarms

The DT Pro Alarm Configuration window is split into two views. On the left are loggers. These may be expanded to show what alarms are defined for them. On the right view are the properties (details) of a selected alarm, if one is not selected (i.e. a logger is selected), a listing of all alarms associated with the logger is shown.

To add an Alarm: Select a logger, right click to bring up options menu, select **Add Alarm**, and choose the alarm type. Enter the set point when prompted (if alarm type requires one). The Device Alarm Definition window will look similar to the screenshot below:



Alarm Types:

- Very High and High: Alarm is raised when the measured value is greater than the alarm set point.
- Very Low and Low: Alarm is raised when the measured value is less than the alarm set point.
- Low Battery: Warning is issued if battery level falls below 10%, alarm is raised at battery level 0%.
- Cal Due: User defines a calibration due date. A warning is issued one week before this date, alarm is raised if Cal due date is reached.
- RF Comm. Loss: Alarm is raised if radio communication is not received for eight data logging intervals or 10 minutes (whichever is greater).

Alarm Properties:

- **Status**: An alarm may be Active or disabled. Disabled alarms are not evaluated. Very Low and Low: Alarm is raised when the measured value is less than the alarm set point. New alarms are disabled by default. Make all appropriate settings prior to enabling the alarm.
- **Set Point**: The value which must be exceeded (either high or low) for an alarm event to begin. Calibration Due Date replaces set point for the Cal Due alarm type.
- **Allowed Excursion Time**: If non-zero, an alarm will not be raised until the set point has been exceeded for at least this time.
- **Recovery Set Point**: The value which must be exceeded (either high or low) before a alarm can be cleared. For High or Very High types, the recovery point must be less than the set point, vice versa for Low and Very Low types.
- **Contact**: An e-mail may be sent to one or more of the system users. System users and their e-mail addresses are defined in Chapter 3: System Security.
- **Recover Mode**: controls how an alarm is cleared. An alarm may be cleared automatically when the value no longer exceeds the recovery set point. In manual mode, the alarm will not be cleared until it is manually acknowledged.
- **Escalation**: Available only if manual recovery (acknowledgement required) is selected. An e-mail may be sent to a system user if an alarm is not acknowledged after a defined time.
- *To edit any property, simply click on it.*
- *Only the properties below that are applicable to the alarm types will appear in the properties list.*
- *Additional users may be declared in the system security as contact e-mail placeholders even if these "users" do not exist or the account is inactive or locked.*
- *Note: a "text message" can be sent to cell phones that support e-mail message reception or by sending the e-mail to an address provided by the cell phone service supplier (e.g. for Verizon subscribers, <cell number>@vtext.com)*

Alarm Declaration and Control:

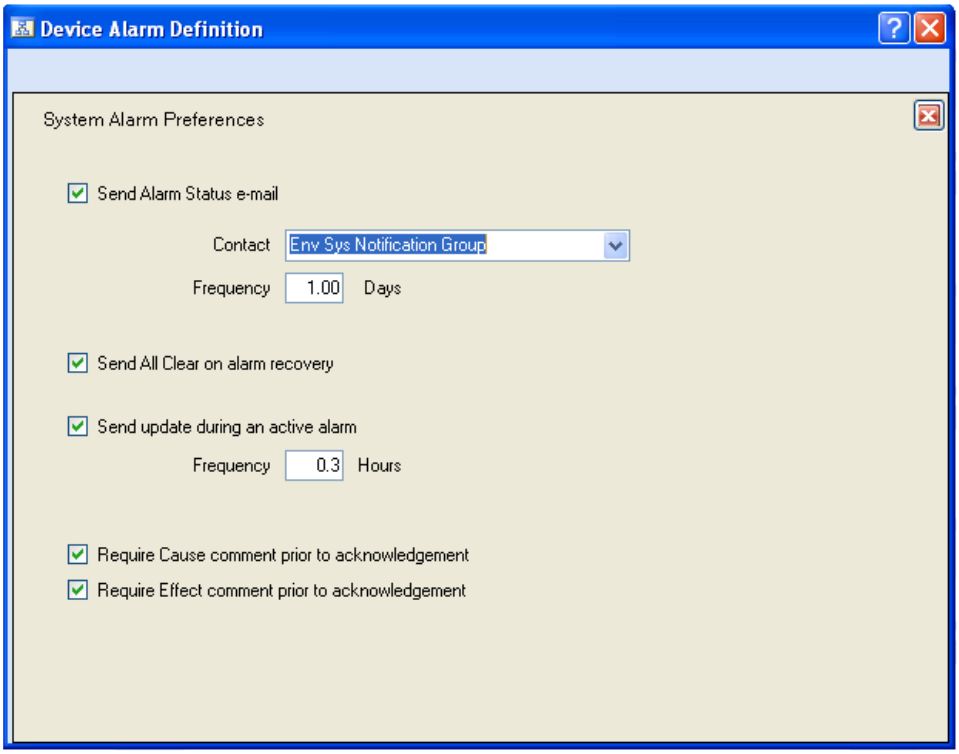
The left side view and its option menu (right click) have the following features:

- The icons show whether a logger or monitor has an alarm.
- The icons show whether an alarm is enabled or disabled.

- Enabled or disabling can be performed for an individual alarm, all the alarms of one logger, or the alarms of the entire group.
- Once an alarm is declared, it may be copied to another logger or to the entire group.
- Alarms may be removed individually, by logger or by type for the entire group.

4.3.3 System 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 unless otherwise noted. See screenshot below:



- **Send Alarm Status e-mail**: if checked, a status email will be sent to the selected contact at the defined frequency. The status will be sent even if no alarms have occurred. *A potential use for this option is to detect computer, e-mail or software failure.*
- **Send All Clear on Alarm recovery:** does not apply to Low Battery or Cal Due alarm types
- **Send Update during an active alarm:** does not apply to Low Battery, Cal Due or RF Comm loss alarm types
- **Require Cause comment prior to alarm acknowledgement:** require the user to enter a Cause comment prior to acknowledging an alarm
- **Require Effect comment prior to alarm acknowledgement**: require the user to enter an Effect comment prior to acknowledging an alarm

4.3.4 Managing Alarms

- If there is an active alarm event, an icon will be displayed on the Wireless Data bar which is always visible.
- If there is an active alarm event, and Wireless data is expanded, the icon of the logger will change to indicate it as the alarm source.

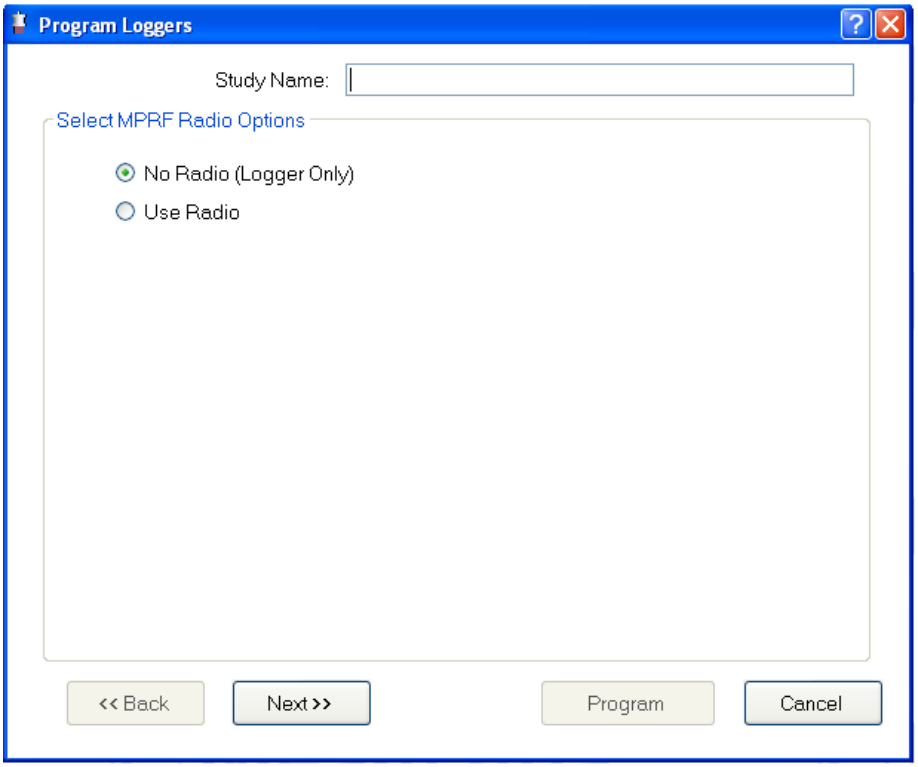
- The Real Time view may be accessed by clicking on a logger or group, and will show alarm status (*see Chapter 6: Receiving and Viewing Radio Data*)
- Clicking on the Real Time view Alarm status column exposes alarm details.
- Alarms which require manual recovery are acknowledged from within the alarm details.
- In Reports, there is an option for an Alarm summary.
- In Reports, an alarm event may optionally be used to generate phase or sub-summaries to facilitate deviation statistics.

See Chapter 8: Creating Reports for details and options regarding alarms reporting.

Chapter 5: Programming Loggers

In this chapter, you will learn in great details the steps involved in programming a logger. Before any logger can log data, it must be programmed. The act of programming a logger tells the logger when you want it start logging data (start time), how fast you want the data to be logged (interval). In addition, you can then program other parameters into the logger to help in the logging, and perhaps, transmitting of data in case of RF loggers used.

Expand **Logger Functions** and select **Program** to start the program wizard. See screenshot below.



You may define a **Study Name** in the top box at any time prior to programming a logger.

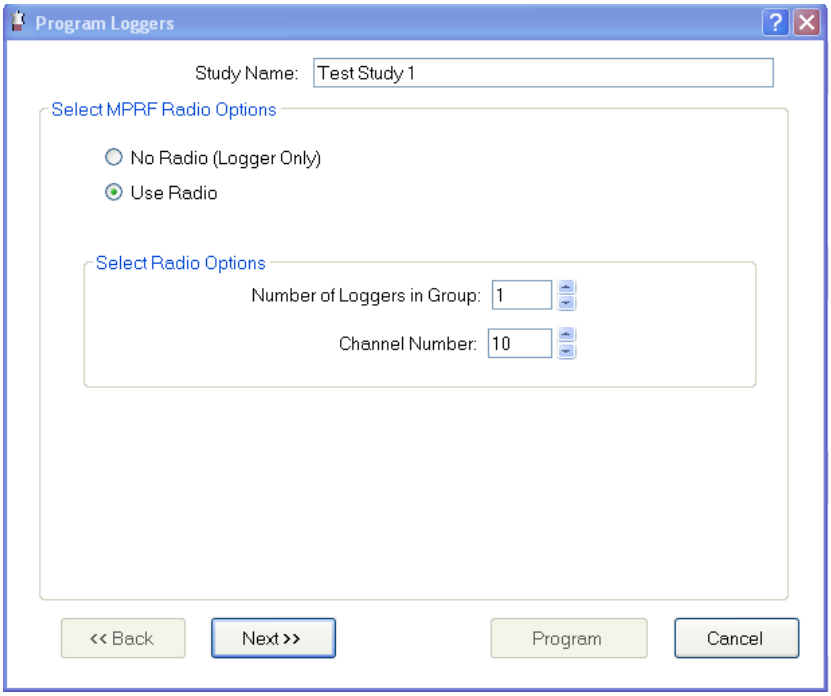
If a study name is not defined, a study is still created and will be named according to the logging start time; see Section 8.4.9: Managing Studies for details.

The wizard consists of three data entry steps. After completing the selections in each step of the wizard, to proceed to the next step, click the Next button.

5.1 Select MPRF Radio Options

If your system has been configured for No Wireless, this screen will not appear.

- Select whether you wish to use the logger's radio or not.
- If radio is used, enter the number of loggers that will be programmed.
- If radio is used, select a radio channel to use; see Section 12.2: Channel Selection for details.

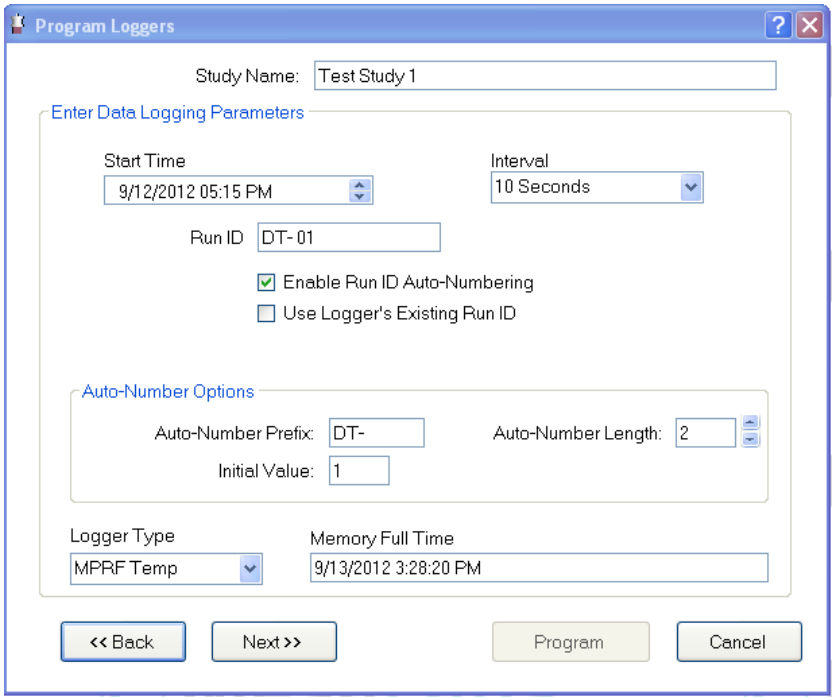


5.2 Enter Data Logging Parameters

- Start Time: The date and time that data logging will begin.
- Interval: How often data will be acquired.
- Run ID: An optional 8 character process identifier which will be stored in the logger.
  - Use Run ID Auto-Numbering: The numeric portion of the Run ID will increment automatically for each logger based on the selected options (options are visible only if auto-numbering is selected).
  - Use Logger's Existing Run ID: The Run ID currently in the logger's memory will not be changed.

Notes:

- *Run ID length is limited to 4 characters on 2 bytes per character computer operating systems such as Chinese, Japanese or Korean.*
- *The logger Type and Memory Full Time boxes at the bottom show when the logger will stop given the selected Start Time and Interval.*
- *How far in the future the default start time is can be configured in system setup.*



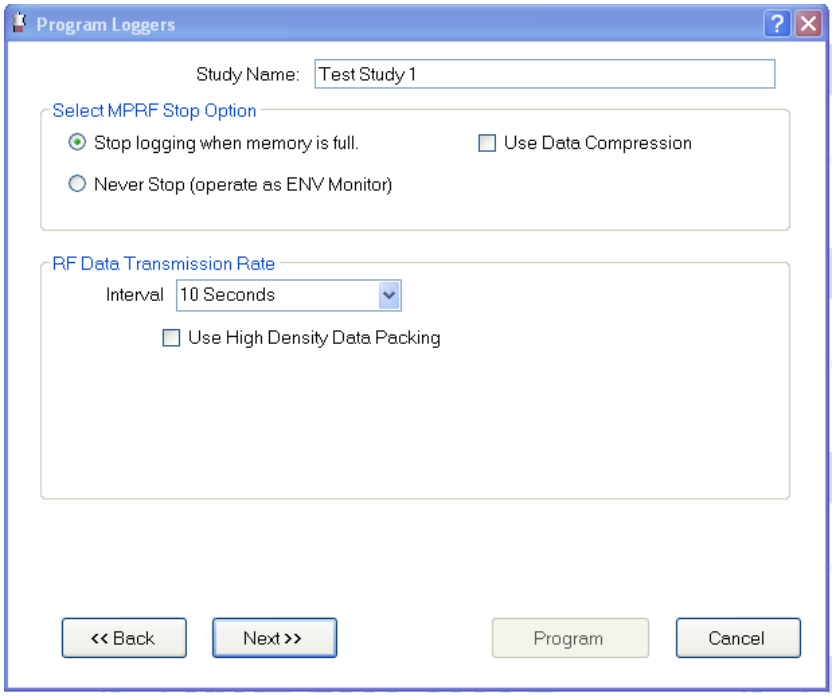
5.3 Select Stop Option / RF Data Transmission Rate

If your system has been configured for No Wireless, this screen will not appear.
These options only apply to MPRF loggers (not to MPIII models).

- Stop Logging when Full: Logger will log points up to its specified capacity (typically 8000 data points for a single channel logger).
- Never Stop: logged data is limited to 1536 time stamped points, newest replaces oldest once 1536 points have been logged.
- Within limits, how often logged data is transmitted via radio is adjustable, see Section 5.3.1: RF Data Transmission Rate for details.

Use Data Compression: Visible only when "Stop when full" mode is used. When selected, allows a MPRF logger with version "T" or newer firmware to log twice as many data points as normal (typically 16,000 pts. for a single channel logger) by compressing the logged data. Logged data will be limited to two decimal places of resolution.

The data transmission rate will usually be the same as the logging interval, but may be less when the interval is short or the number of loggers is large.



5.3.1 RF Data Transmission Rate

Each MPRF Logger requires a specific time slot for communications to occur after the Logger logs data. This time slot is assigned automatically by DT Pro. Normally, two loggers can communicate data within 1 second, in **High Density Data Packing** mode; four loggers can communicate per second. The total amount of data points that can be reliably communicated depends both on the total number of loggers and on the data logging intervals of these loggers.

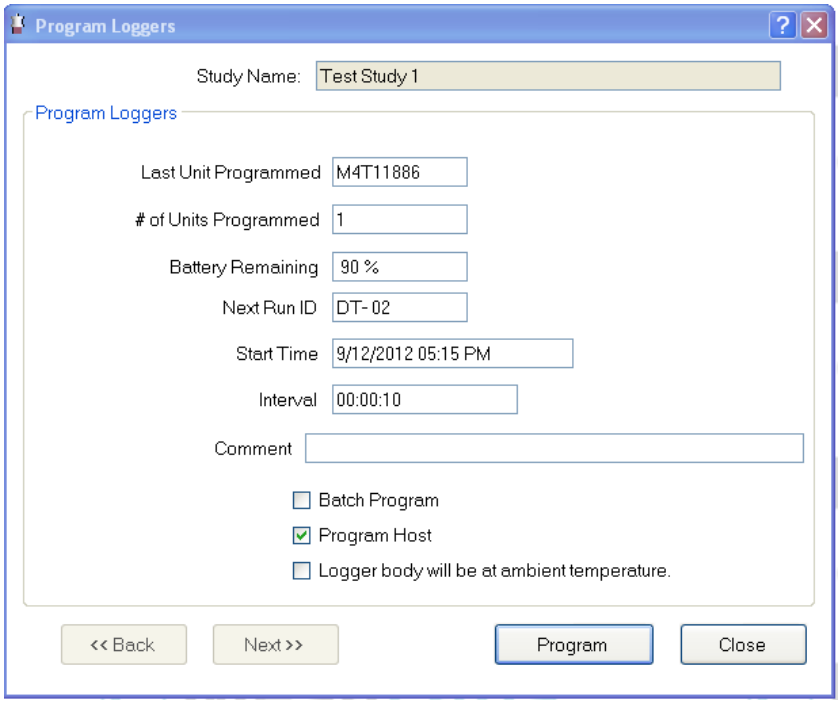
The radio protocol used allows for the retrieval of any missed data points. This retrieval process also has limits. It is possible to have a group of loggers sampling at short intervals that acquire data faster than it can be transmitted. This situation will be indicated in the RF data transmission rate status box.

From the number of loggers being programmed, the selected interval, records or RF receptions from other active loggers, DT Pro determines a minimum allowed data transmission interval using standard data packing. High Density Data Packing may be selected to allow a reduced transmission interval, but there will be a decrease in RF comm. reliability.

5.4 Program Loggers

- Place a logger in the interface.
- If desired, enter or change the Run ID to be loaded in this logger.
- Click the Program button. Remove the logger from the 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 may be used to indicate programming success or failure if so selected in the system setup
Programming a logger which has not had its current data downloaded will result in a warning message; this message can be disabled in the system setup.



5.5 Program Options

- **Batch Program:** If selected, when "Program" is clicked, an automated detection process will begin and the "Program" button will change to "Stop". When the programming parameters have been loaded in the logger, remove the logger from the interface and place another logger in the interface. It will be loaded without need for further button clicks.
- **Program Host:** Select this option if you have chosen a different radio channel (or for first time use). The selected channel will be loaded into the host radio receiver.
- **Logger body at ambient temperature.** Select this to improve radio performance if the measured temperature will be very hot or cold, but the body of the logger will be near ambient temperature (*does not apply to MPIII models*).
- **User Comment.** Prior to programming, a comment can be entered. This comment will be associated with the programmed logger and be visible in the program and other reports. It will also be visible when the logger is read, and may be edited (or entered) either at that time or in the final report (summary view). *Notice: the comment is not loaded into the logger, it remains resident only on the computer; if the logger is read on a different computer, User Comment will not be available.*

If Program Host is not selected, a warning message will be displayed in the event that the selected radio channel does not match the Host's current channel (and radio use has been selected).

5.6 Miscellaneous Details

- The Program Logger Wizard will not allow changing the start time or interval once one Logger has been programmed. To do so, you must close the Program window and start over.

- In the event the start time elapses, 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.
- RF 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 logger's memory.
- A list of the programmed loggers will be visible in the Logger Functions browser view (under Current Session). A **Program Report** can be directly accessed from this view (right click to open pop up menu).
- In general, RF loggers must be programmed on the computer where RF data will be received. If it is desired to program loggers on one computer, and receive RF data on another one, both systems must be configured with the same **RF domain name**; see Chapter 2: System Setup for details on RF domain name configuration.

5.7 Logger Interval Control via RF

The data logging interval may be changed via RF. This is performed by expanding **Configuration Tools**, selecting the desired logger (or its group) in the browser view, right clicking to bring up the options menu, and selecting **Configure Device**. In the device configuration window, click on the interval column and set the desired interval.

Warning: How an interval change is implemented is dependant on the selected stop mode.

If the logger was programmed using the "**Never Stop**" mode, logger operation is identical to an environmental monitor, and all data points are also time-stamped internally. Reading the logger will result in a data set that has two different intervals (as expected). The interval that is displayed on reports is report template dependant.

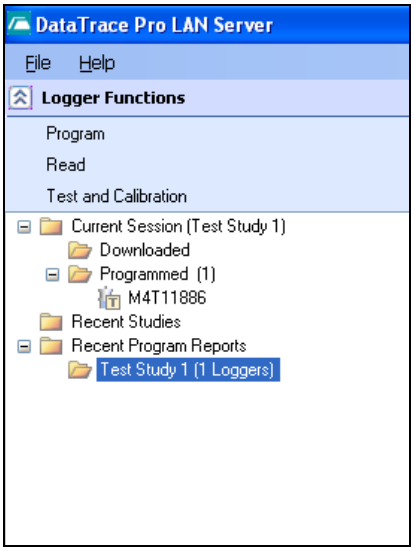
If the logger was programmed using "**Stop When Full**" changing the interval dynamically will also **reset the logger start time** (it will be the time the command was received rounded up to whole minutes). If data is subsequently downloaded from the logger, it will start at this new time, not at the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

There is no facility in DT Pro to set a new Start Time via RF. If such functionality is desired, it can be replicated by using the Read Time Range feature or by many other means associated with report creation.

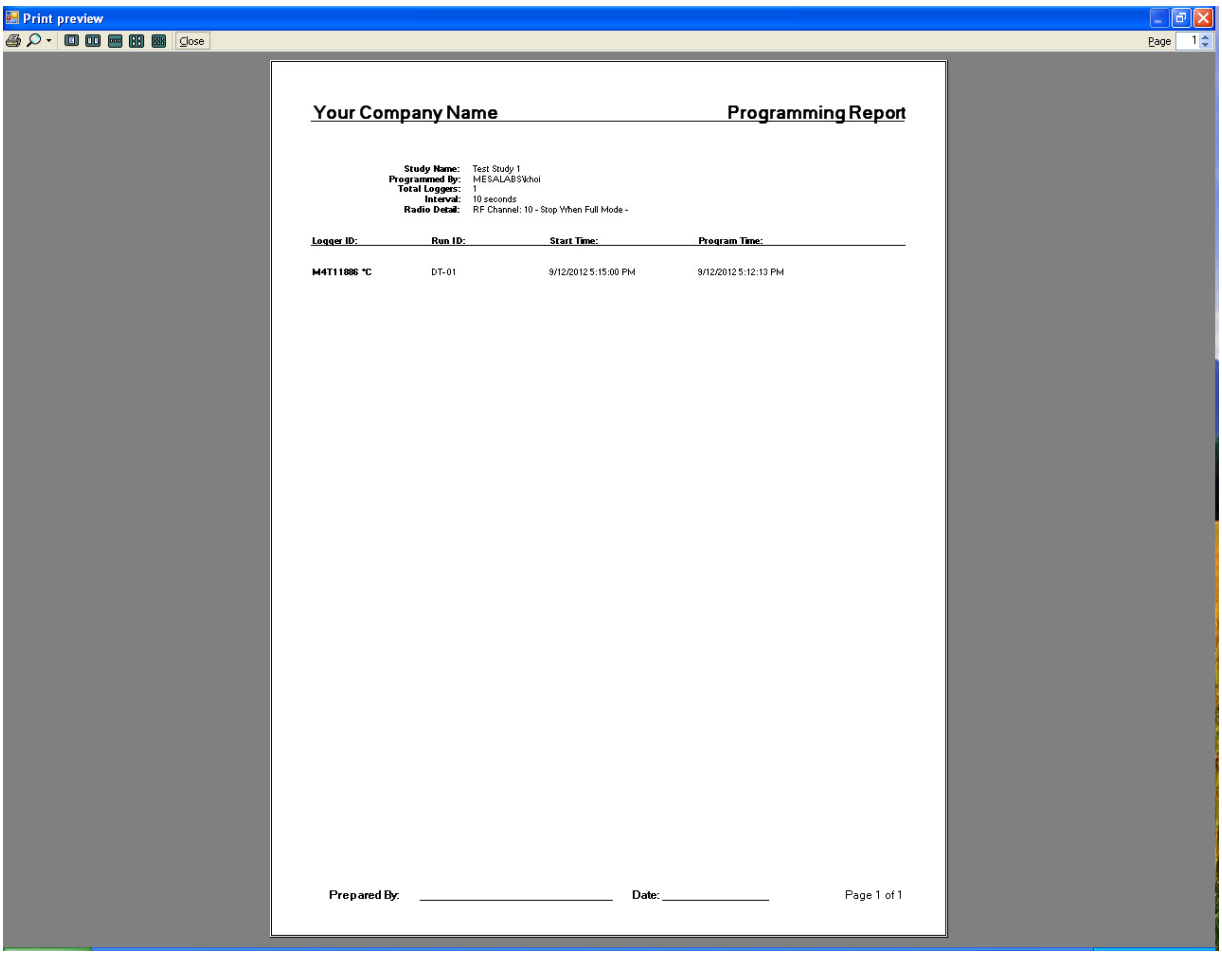
Programming loggers is an audited event and may require a digital signature.

5.8 Programming Report

After a successful programming session, a program report for that session can be obtained. On the left side of the DT Pro window, with the Logger Functions category expanded, click to expand the Recent Program Reports folder, see below:



Select the study of interest, then right-click on the study, and then select Display Program Report menu option. A preview of the programming report will appear momentarily, as shown below:



This report contains details of the program settings that have just been programmed into the logger.

Chapter 6: Receiving and Viewing Radio Data

Once an RF logger has been successfully programmed, the logger will now start transmitting data, even before start time has elapsed. The logger will only start logging data once start time commences. When data points are transmitted via radio, how do we go about receiving radio data and displaying radio data? This chapter will go into details on this subject.

In order to receive radio data, there must be at least one loggers or environmental monitor transmitting data. The process of starting data transmission for these devices is described in Chapter 5: Programming Loggers.

6.1 Database Integrity Control

DT Pro **will not** display or save data, nor allow control of an "unknown" logger or monitor. Normally, the act of programming, reading or testing a logger demonstrates ownership and identifies the logger to the system. Environmental monitors or Repeaters must have their serial numbers manually added. It is possible to receive radio data from a logger that was programmed on a different computer; if the two computers share the database via LAN, there are no issues; if not, the logger must be manually added.

The following is required for new Environmental Monitors or Smart Repeaters / Routers

Adding a New RF Device: Expand **Configuration Tools**, right click within the browser view to bring up the menu and select "**Add New RF Device**". Enter the Serial Number of the logger, monitor or router when prompted.

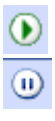
Access to Configuration Tools is restricted to users with Admin or Power User permission levels.

6.2 Radio Channel Control

- In order to receive radio data, both the transmitter and receiver must be on the same radio channel (frequency).
- When programming loggers, a channel is selected and the host receiver may be programmed to use the same channel.
- Channel identification is semi-automatic for environmental monitors or router if there is an active host receiver. *See Section 4.2: Configuring Monitors, Routers and Repeaters.*
- The channel of the host receiver may be set manually from within the Test window.
- The channel of the host receiver may be set manually from Configuration Tools, expanding Routers, selecting the host receivers, right clicking to bring up the menu, and selecting **"Set Host Channel"**
- The data logging interval for a logger may be changed via radio from the Device Configuration window (*for access details, see Section 4.1: Managing Groups and Tags*).

6.3 Radio Reception Control

The two buttons on the Wireless Data bar control radio reception.



Start RF Reception

Stop RF Reception

If Auto-Start RF was specified in the System Setup, RF reception will already be active.
If viewing RF data from a remote database, these buttons will be disabled.

6.4 Viewing Radio Data

To view radio data, follow the steps below:

1. Click the Start RF reception button
2. Expand Wireless Data (if not already so).

Options for sorting by a group, Run ID, a study or simply viewing all active RF loggers can be set by right clicking on the file browser.

Select a group of loggers or monitors, an, individual device within a group, or a study. Click on the desired item. The Real Time View window will open on the right.

The Real Time View window provides 3 ways to view the data.

Notes:

- *Any of the views can be copied and subsequently pasted into another application.*

- *For more advanced data processing such as viewing a lethality calculation for the received data to date, access the Reports and select data from groups over the desired time range (requires the loggers have been assigned to one or more groups); while doing so, RF data is still received and saved.*

6.4.1 Detail Tab

Shows current data and status, including

- Serial Number or Tag ID (*per display setting of wireless browser menu*)
- Last Timestamp
- Data value
- Alarm Status
- RF Communications Status
- Battery %
- Elapsed time since last communication (receiving PC only)

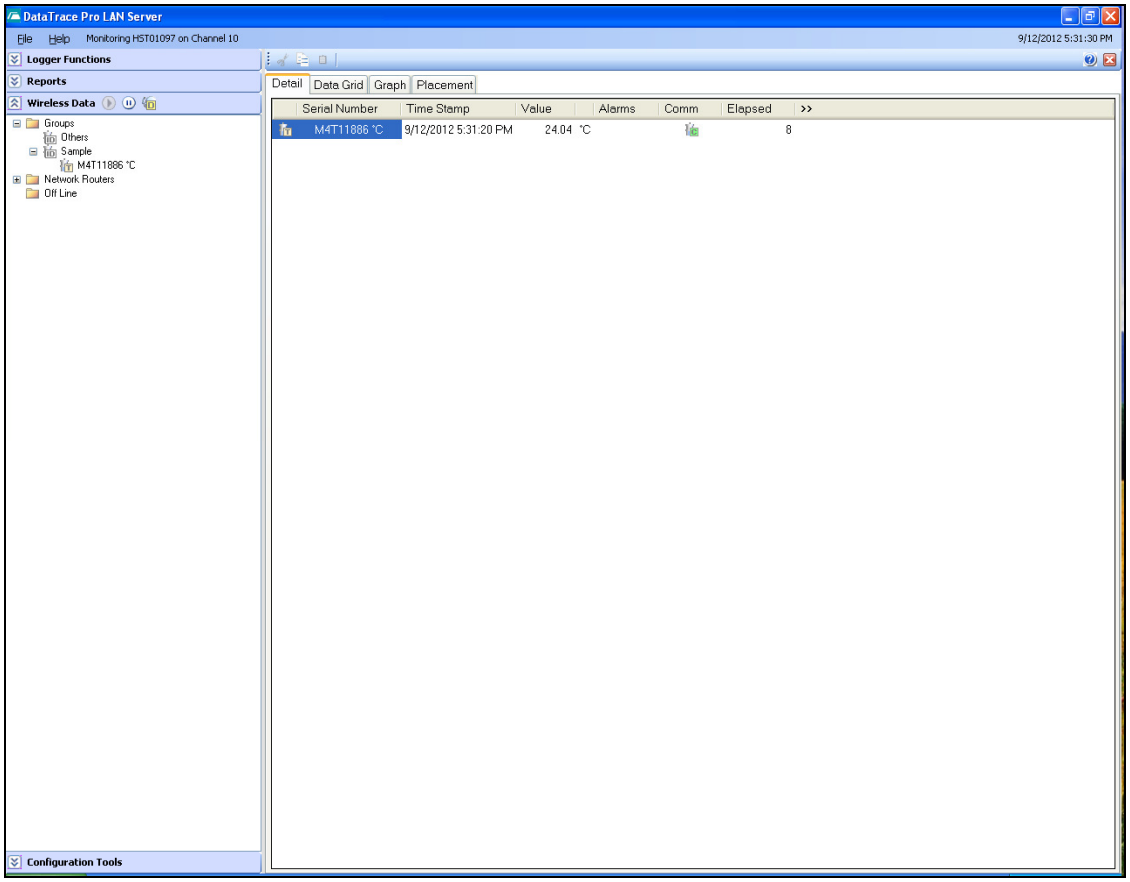
Additional items (if view is expanded using ">>")

- Start Time
- Interval
- Run ID
- RF Signal strength
- Logged readings

Alarm Status Icon: Displays three states: Green indicates no alarm occurring. Red indicates an alarm is active or not yet acknowledged. Yellow indicates transitional states (e.g. a set point excursion where the allowed time has not yet been exceeded, or, an acknowledged alarm that is still in excess of its set point).

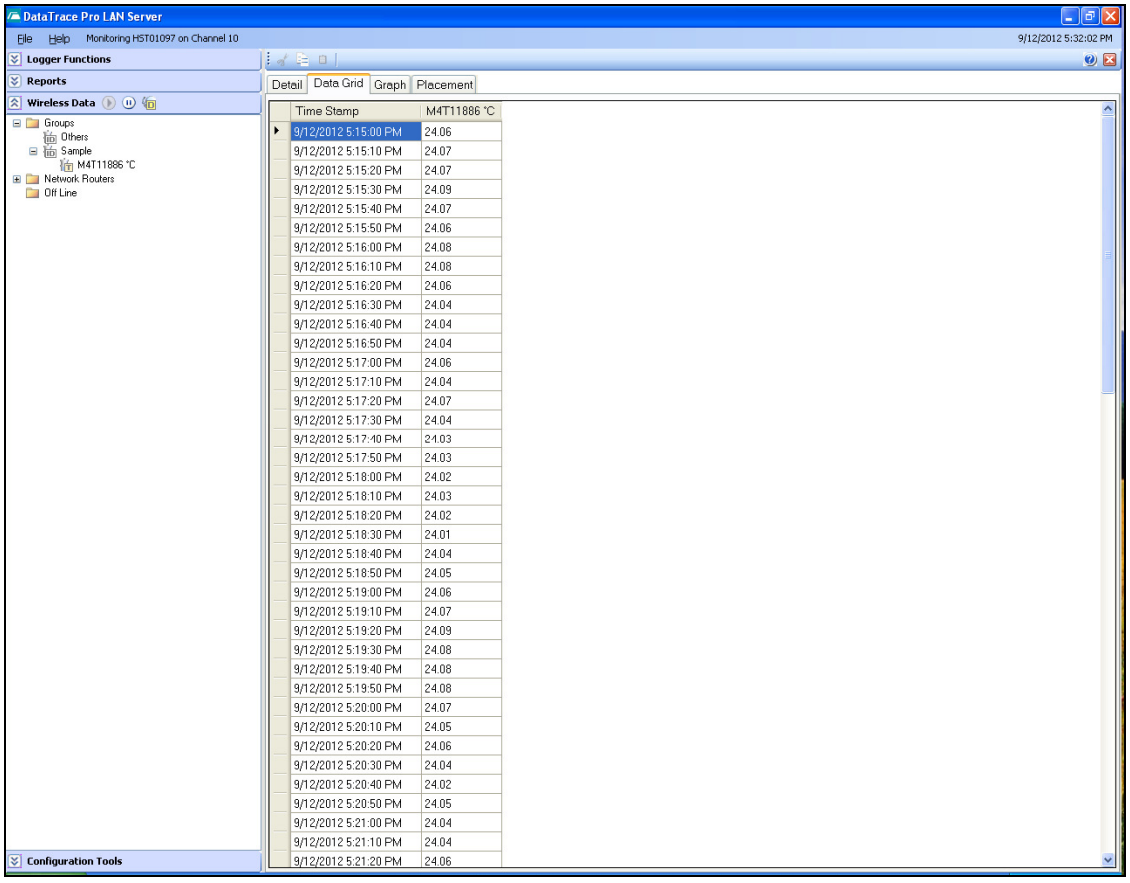
RF Communications Status Icon: Displays three states: Green indicates normal communications. Red indicates communications failure (no data reception for 8 intervals). Yellow indicates marginal communications (e.g. data reception accompanied with the inability of the logger to receive a command, or, no data reception for 4 intervals).

Clicking on the Alarm Status column or an individual item exposes Alarm details and properties. See below.


DataTrace Pro LAN Server
File
Help
Monitoring HST01097 on Channel 10
9/12/2012 5:31:30 PM
Logger Functions
Reports
Wireless Data
Groups
Others
Sample
M4T11886 °C
Network Routers
Off Line
Configuration Tools
Detail
Data Grid
Graph
Placement
Serial Number
Time Stamp
Value
Alarms
Comm
Elapsed
>>
M4T11886 °C
9/12/2012 5:31:20 PM
24.04 °C
8

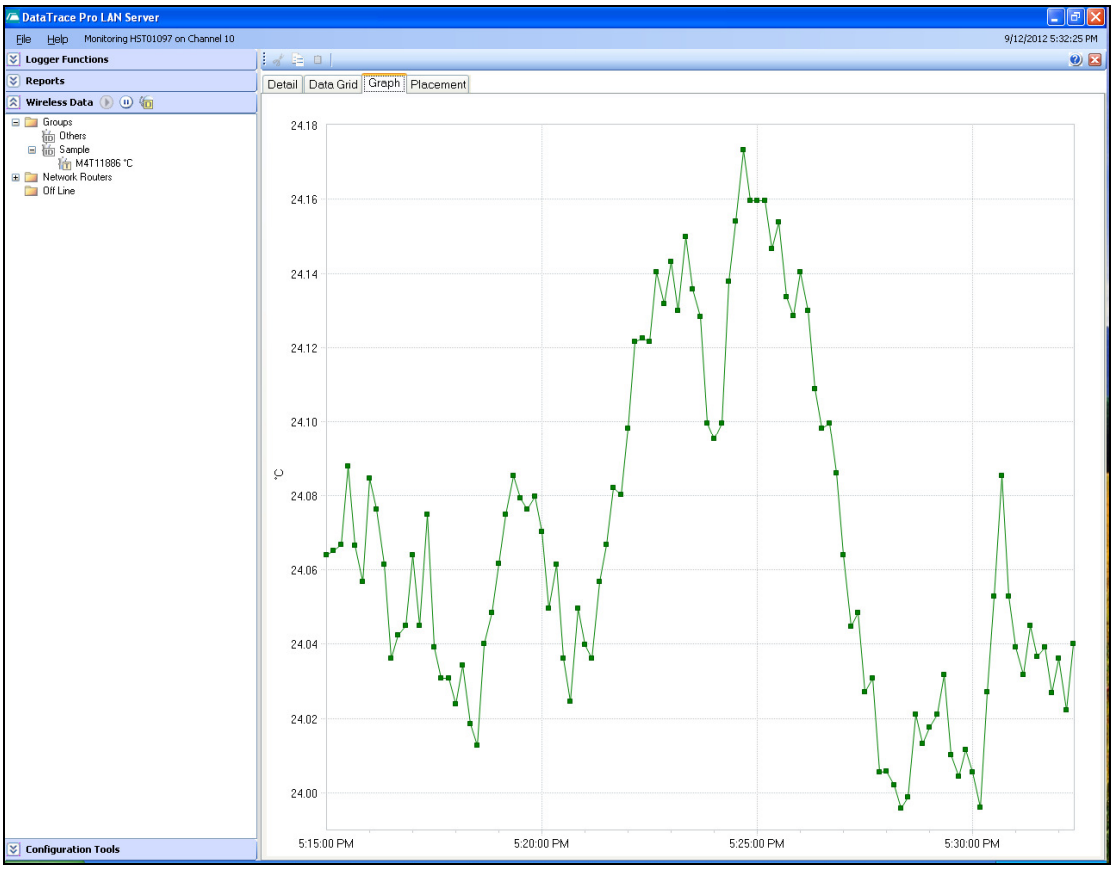
6.4.2 Data History Tab

- Contains a grid view of recent data values.
- *New rows will appear in the grid as new data arrives.*
- *Data history goes back as far as is defined in the system setup.*



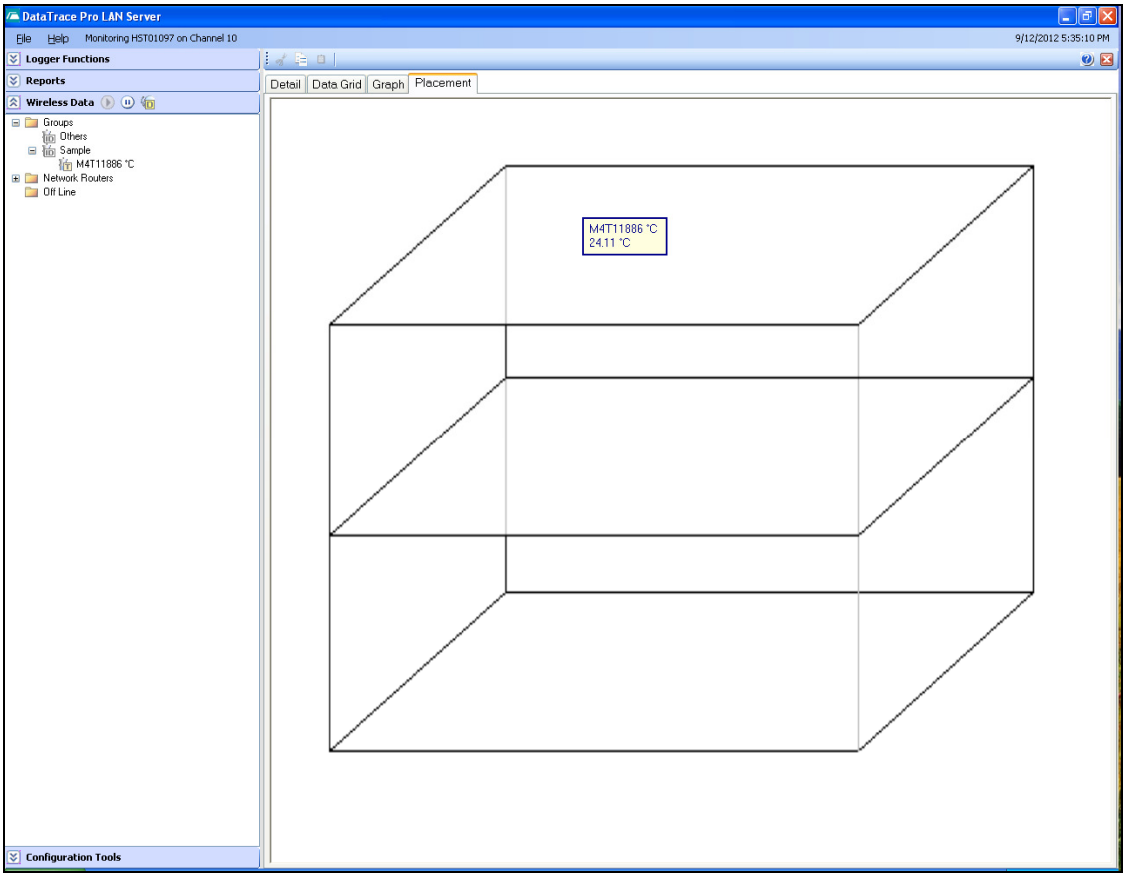
6.4.3 Graph Tab

- Contains an XY graph of the Data History grid
- *Graph will update as new data arrives.*
- *Use the mouse to zoom in on data of interest.*
- *Right click on graph to expose options menu, scale axis, un-zoom and other options.*



6.4.4 Placement Tab

- Overlay view of loggers or monitors on a user provided map or picture
- Use the mouse to drag and drop loggers or monitors to the desired positions.
- Right click on placement view to expose options menu, which includes:
  - Import or clear the background picture, drawing or map
  - Auto-arrange the logger or monitors
  - Display options, including value only, serial number or tag, Run ID or logger properties



6.4.5 Study Manual Control

A study can be created and/or controlled while receiving real time radio data. The icons which provide control will be visible only if it is allowed (in System Setup, Preferences), and access to the real time data view was via the selection of a named study (the Sort by Study option must be selected when accessing the real time view window, right click on the Wireless Data browser to expose the options menu). This control only applies to specifically named studies; that is, when the loggers were programmed, the study name field was not left blank. Un-named studies will not be available for selection.

Use the study icons at the top of the Real Time view to set or edit a study name, and then start the study at the desired moment. Once the process is complete, stop the study. The study record is created when the Stop study button is used. It is always advisable to inspect the data; if all data was received via RF, there is no further need to read the loggers. Once one study has been stopped, a new study name may be defined, started and stopped if desired. Depending on the system security settings, a digital signature may be required when starting or stopping a study.

A study is not finalized (that is, is not available for selection as a "Recent Study") until either the study has been stopped or the logger has been read. These events mark the end of data time. The start of data is defined by either the logger's program time or by the time the Study Start button was clicked.

A study that does not yet have a defined stop time will be a member of the "Active Studies" folder. Once a stop time has been set, it will be under "Recent Studies". A finalized of "Recent Study" cannot be re-started; however, if the loggers of this study are still active, the study name can be edited and a new study manually started (and eventually stopped).

Starting or stopping a study does not affect data acquisition (data logging by the logger or the saving of received radio data); it is only setting the data start time, end time and members for the study. It is always advisable to inspect the real time data; if all data was received via RF, there is no further need to read the loggers.

When a logger is read that already has had one ore more finalized studies defined for it, all logged data will be displayed, but the start and stop time (or times) will be graphically indicated. When a "Recent Study" is accessed for reporting purposes, only the data inclusive of the defined times will be shown.

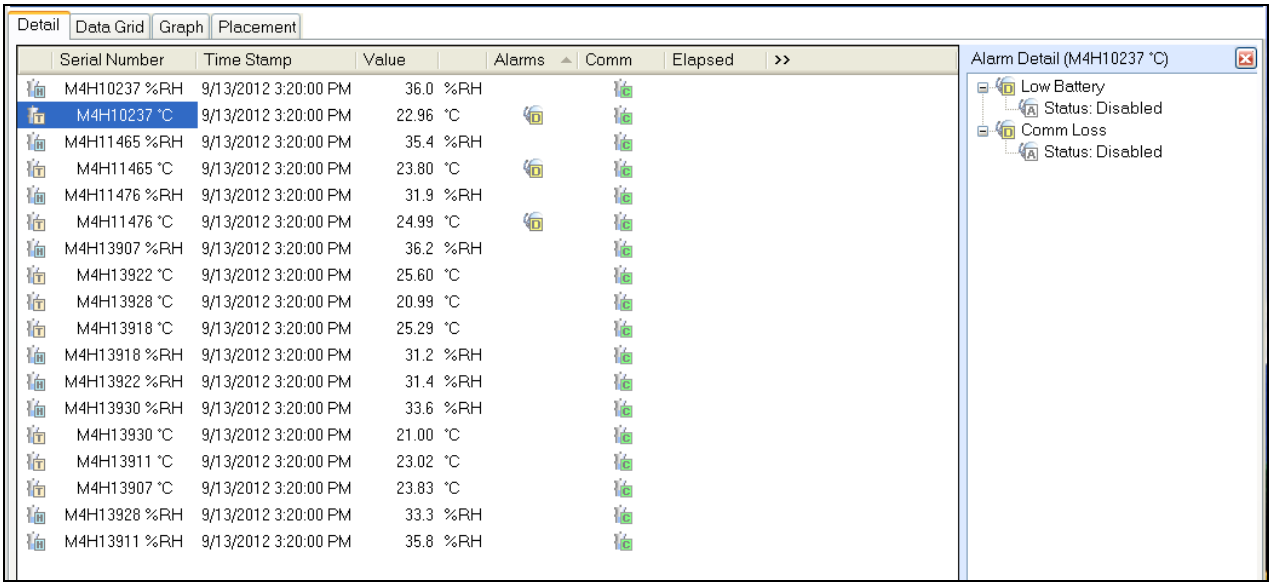
By default, when a logger is read, all logged data will be both displayed and saved. If for some reason it is necessary that data that is not part of a study not be in the database, when reading loggers use the Preview button and Read by Time Range options set to match the study start and stop times (see Chapter 7: Reading Loggers). If RF data was received (which is always saved unless the logger was RF disabled), it must be manually deleted by a system administrator (most easily accomplished using the delete data option in the Graph of the Reports View).

See also Section 8.4.9: Managing Studies for details on other methods of creating or managing studies.

Note: there are no restrictions on study names or their duplication; to prevent confusion, study name duplication should be avoided.

6.4.6 Alarm Control

Clicking on the Alarm Status column or an individual item exposes Alarm details and properties.
The current alarm settings can be viewed.
If and alarm is occurring for a device, the status of each alarm is displayed



Alarm Acknowledgement:

1. In the Alarm detail, select the alarm to be acknowledged.

2. Right Click to expose the alarm control menu. Click on Acknowledge Alarm
3. Enter a comment regarding the alarm when prompted (optional).

See Section 4.3 Configuring Device Alarms for complete alarm information.

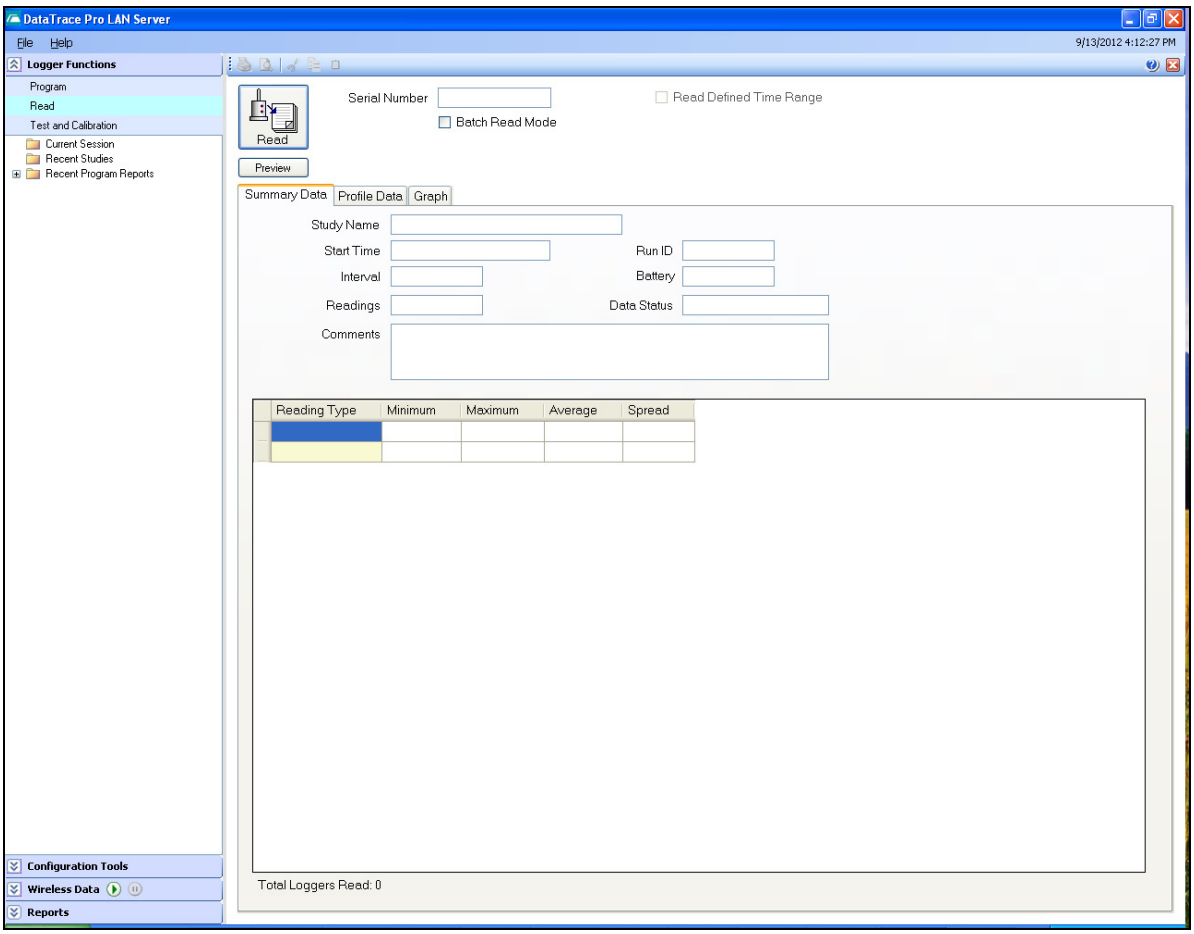
Chapter 7: Reading Loggers

Normally, with RF loggers, there would not be a need to read them. However, DT Pro also supports non-RF logger type, i.e. MPIII loggers. In this chapter, you will learn the details on how to read one logger, or a batch of loggers.

To start the logger reading process, expand **Logger Functions** and select **Read.**

If your system has been configured for Environmental Monitors Only, Logger Functions will not be visible.

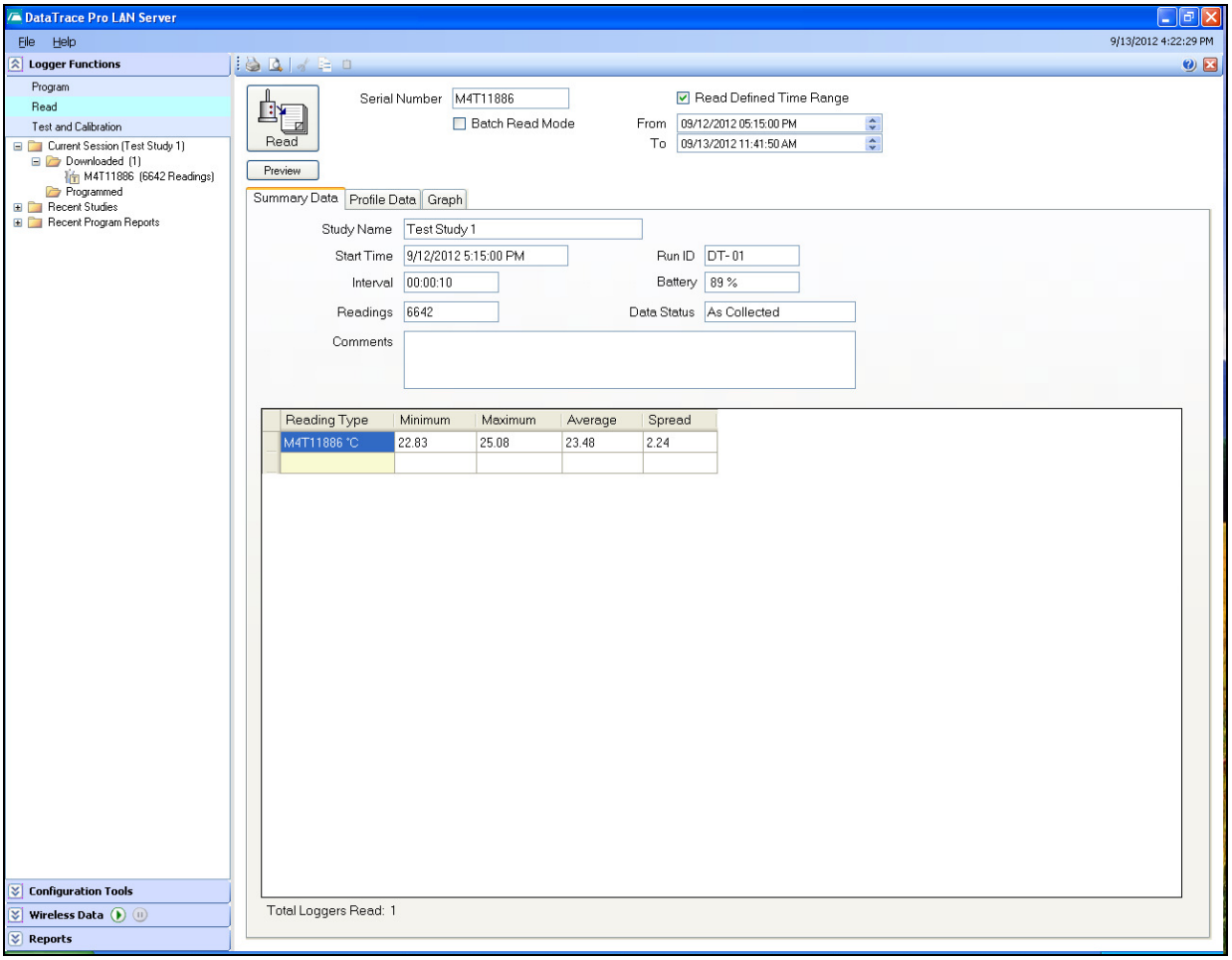
The Read window below will appear:



7.1 Standard Read

1. Place the logger in the interface.
2. Click the "Read" button.
3. When download is complete, view the logger data.
4. To read another logger, place next logger in the interface and click "Read"

Shown below is the Read window after a logger as been read:



7.2 Batch Read Mode

To enable batch Read mode, make sure the “Batch Read Mode” option is selected prior to reading the first logger. Then follow the steps below:

1. Place a logger in the interface.
2. Click the "Read" button.
3. When download is complete, remove the logger from the interface
4. Place next logger in the interface; it will be detected and downloaded automatically.
5. When all loggers have been read, click "Stop".

Notes:

- *If different types of loggers are to be read, read one type first, then "Stop" the batch read process, change the Logger type, and re-start the read process.*

7.3 Read 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.*

Preview: Same as Single Logger Read; however, the data is **NOT** saved in the database. The data may then be inspected and the desired time range determined. Data acquisition is stopped.

Read Defined Time Range: 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 logger has either 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 logger.

Setting the From and To Range:

1. The default date and time will be the first and last data point of the first logger that is read or previewed. If "Read Defined Time Range" is selected after reading the first logger of a group or study, all subsequent loggers will then have matching last data points (eliminating data that is logged while others are being read).
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. 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".
4. Once a From and To range has been created, From and To marker lines will appear on the graph. These lines may be dragged and dropped in order to adjust the From and To range.
5. Should the logged data contain two (or more) distinct processes, it is allowed to set a time range that focuses on one process, read the 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 from other than these studies will not exist in the database if "Preview" is used to set the time ranges).

Once a data time range has been set, the batch read mode may be used if desired.

7.4 Read Views and Detail

There are three tabs in the Read window: Summary Data, Profile Data, and Graph

- **Summary View**: Shows programming details and data statistics.
- **Profile Data**: A grid showing the actual time-stamped data values.
- **Graph**: Graphical display of the data with zooming and axis scale control (right click on graph to expose menu).

- Data from any of the views can either be **printed or copied** (for subsequent pasting into another application) by using the top menu bar icons.
- If there already exists a defined study for the data set (via Study Start / Stop control of RF loggers), the study range (or ranges if there are multiple studies) will be indicated by vertical study line markers.
- **Calculations** such as Lethality or MKT will appear in the summary view if so defined in the system setup.
- The Current Session browser view will show which loggers have been read, and which have not.
- If a **Comment** was entered when the logger was programmed, it will be displayed in the summary view. The comment may be edited, or a new one added if desired. Comments can also be entered or edited in the summary view of a report.
- An attempt to close the read window before reading all loggers that where part of a study or program group will generate a warning message.
- When all loggers have been read, a report for the entire batch or study can be instantly accessed by selecting Current Session or Recent Studies in the browser view (right click to expose selection menu)
- Labels or arrows may be added to the graph; these are inserted in the same manner as the more advanced Reports Graph.

7.5 Reset and Data Recovery

Loggers may on occasion reset during operation. When this occurs, the logger stops logging data. A "Reset" may 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. How this data is recovered depends on the model of the Logger.

- MPRF Loggers: If recoverable data exists, it is recovered automatically after notification of the Reset event.
- MPIII 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).
- In all cases of data recovery, the data is tagged within the audit trail portion of the database to indicate this condition.

Notes:

- *MPRF loggers may also undergo a radio reset caused by insufficient battery power to operate the radio. When this type of reset occurs, radio transmissions cease but data logging continues. When the data is downloaded, a notification message is generated. A radio reset most commonly occurs when using loggers with the radio enabled in ultra-cold environments.*

- *Reading loggers is an audited event and may require a digital signature.*

Chapter 8: Creating Reports

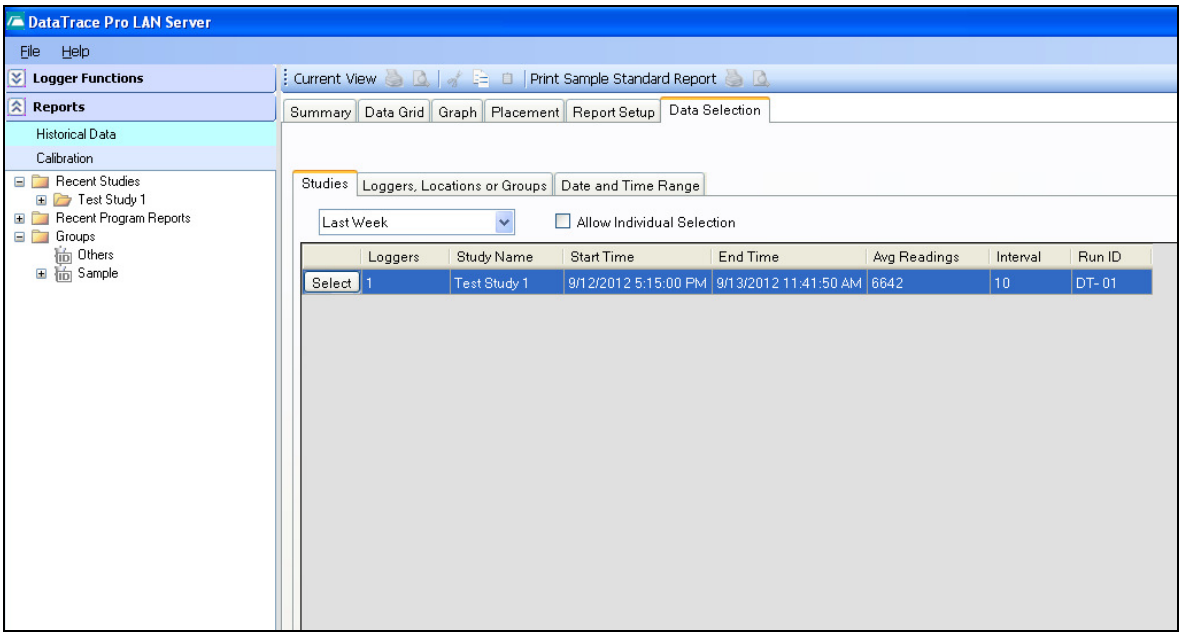
DT Pro offers an extensive and feature-rich reports module. It offers users great flexibility to customize report templates to fit their companies' needs. In this chapter, you will learn in great details how to setup a report template, and then use that template to generate meaningful reports from the data collected from loggers.

8.1 Data Views and Reports

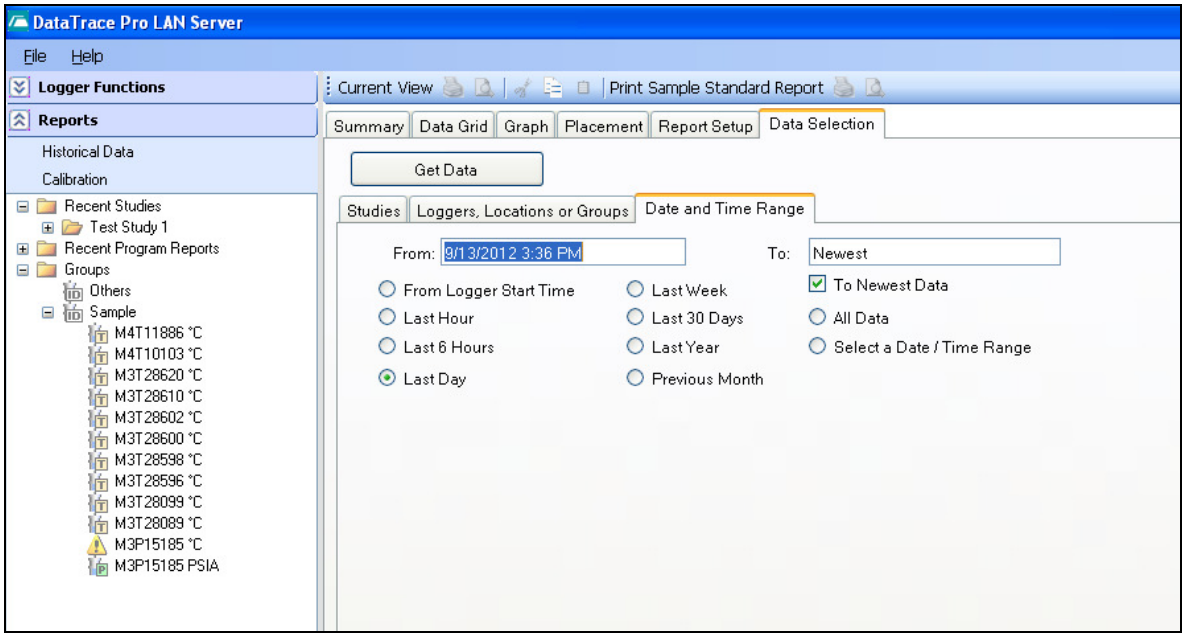
There are many types of reports in DataTrace Pro. The most common way to view data and/or generate a report is to access the Data View window. *(Miscellaneous types are listed below in another section)*

The first step in viewing data or creating a report is to define a data set, namely, one or more loggers or monitors with data starting and ending at defined times. Each of the methods below opens the Data View window, but the data set is potentially different:

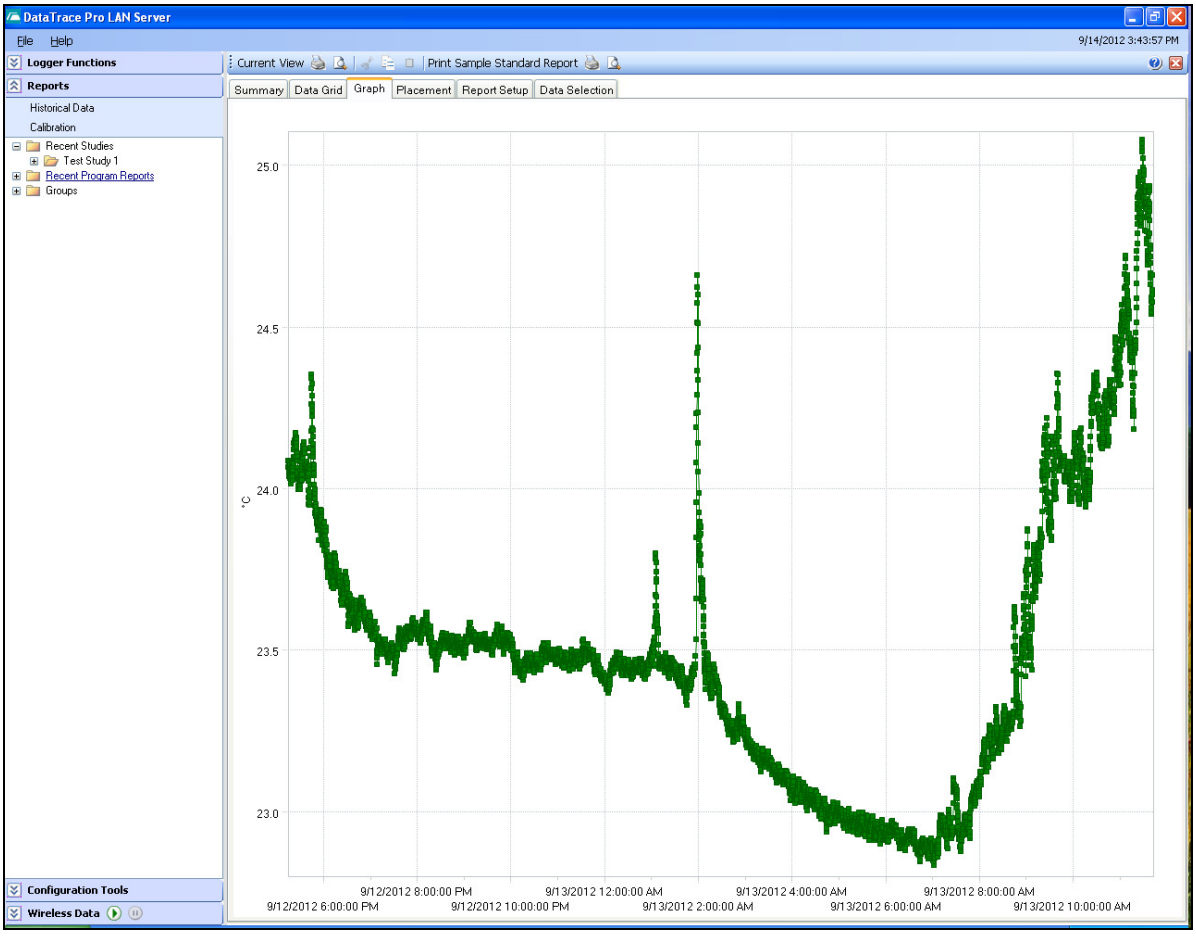
- Expand Reports category, click Historical Data. User must select a study or choose the loggers and set a data time range. See below for a screenshot of this view:



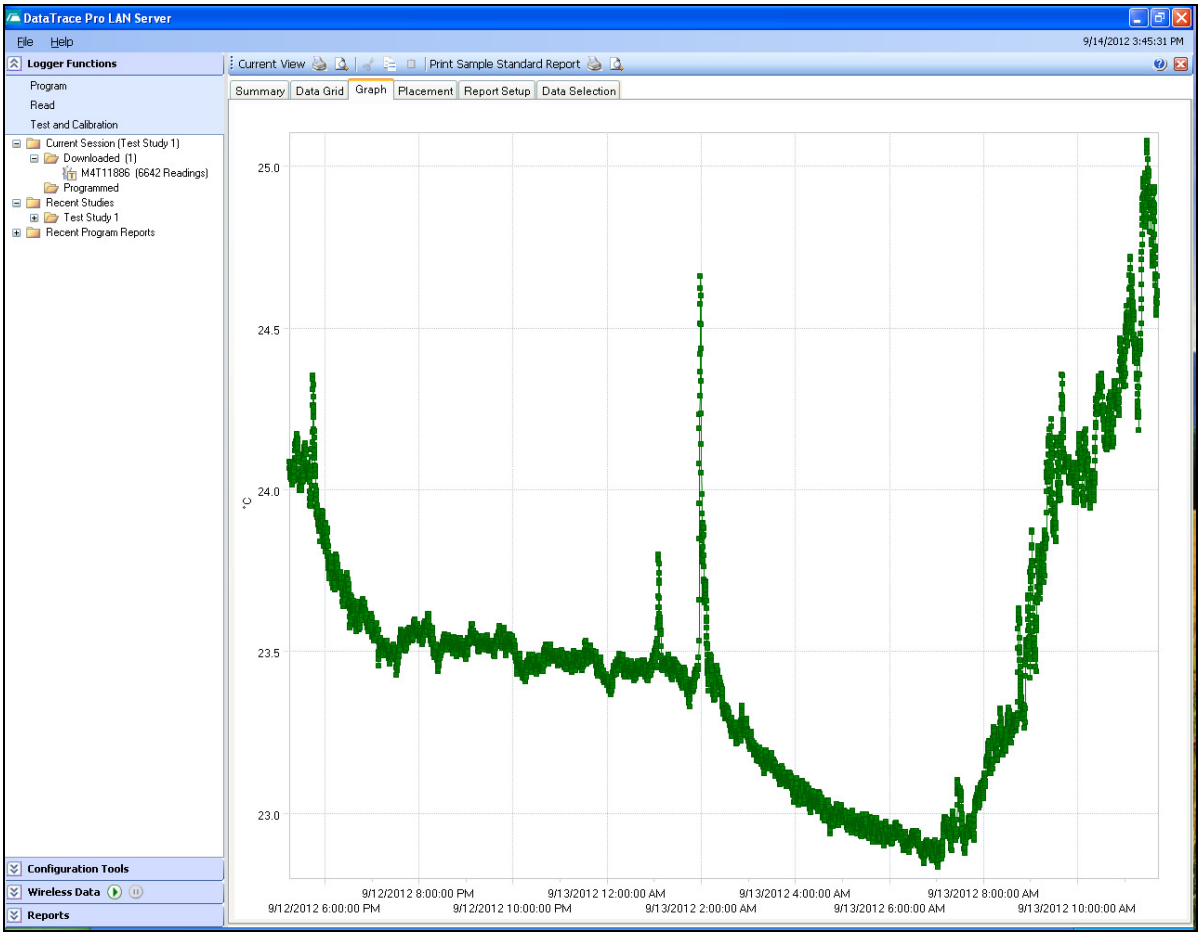
- Expand Reports category, select a logger or group, right click for options menu, and select Display Data. The loggers are defined, but the user must select the data time range. See below for a screenshot of this view:



- Expand Reports or Logger Functions category, expand Recent Studies, select a study, and right click for options menu, select Display Study or All Studies. Loggers and time ranges are pre-defined. What you will see is a graph of all data that appears right away once the Data View window is launched. See screenshot below:



- After reading a group of loggers, select Current Session > Downloaded, right click for options menu and select Display Study. Loggers and time ranges are pre-defined. What you will see is a graph of all data that appears right away once the Data View window is launched. See screenshot below:



8.2 Selecting Data

The data selection process involves creating a data set consisting of data from one or more loggers, all or some of their channels, with a defined start and end dates and times for the data. There are several ways to accomplish this. The easiest is to access data via a study, which is a predefined group of loggers and date / time range. A second method is to manually select loggers and channels, and then select starting and ending times for the data. It is also possible to select some larger group of loggers and time ranges known to encompass the data set of interest, and subsequently remove any undesired loggers or data range.

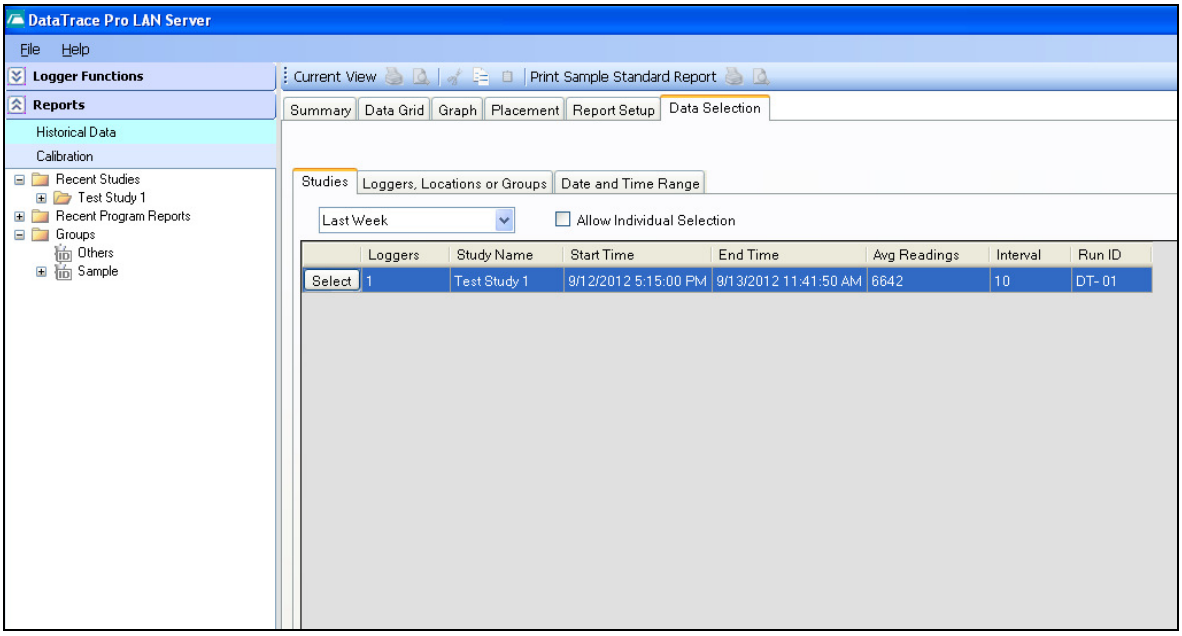
Data sets are created in the Data View window, Data Selection tab.

8.2.1 Select by Study

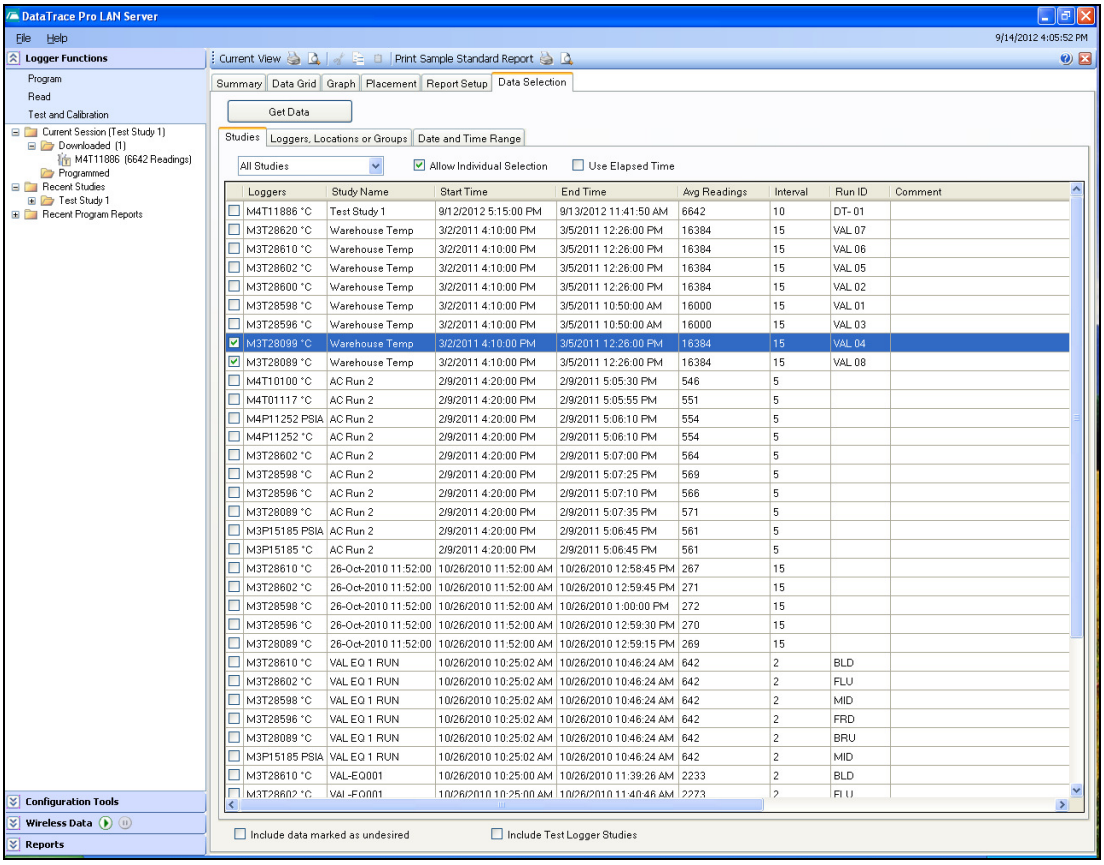
Studies are created in various ways, the most common is defined by a group of loggers programmed to collect data at the same time, and subsequently read (downloaded) at the same time. *See Section 8.4.9: Managing Studies for other methods.*

- In the **Studies tab**, a grid indicates the available studies, the study name (if one was defined), the number of loggers (channels) in the study, data start and end times, average data readings per logger, data interval and Run ID.
- Using the **drop-down box**, the displayed studies may be all available or more recent ones (by month or by week).
- A study is also created when loggers are tested; these **"test" studies** are not displayed unless their inclusion is specified by using the check box.
- Click the **Select** button to access the desired study.

  See blow for screenshot:



- If the **Allow Individual Selection** check-box is used, the studies are expanded to show the constituent logger channels. Place a check mark next to the desired logger or loggers and click the **Get Data** button when finished choosing. See screenshot below:



- If the Allow Individual Selection check-box is used, the **Use Elapsed Time** option will be available. This option allows data from different studies (e.g. acquired on different days) to be overlaid in time in order to compare process or other differences. The **Time Sliding** control (accessed from the Graph Data options menu) allows the user to manually adjust or "slide" elapsed time data from one logger relative to others so as to align the different data sets and efficiently compare or measure process differences.

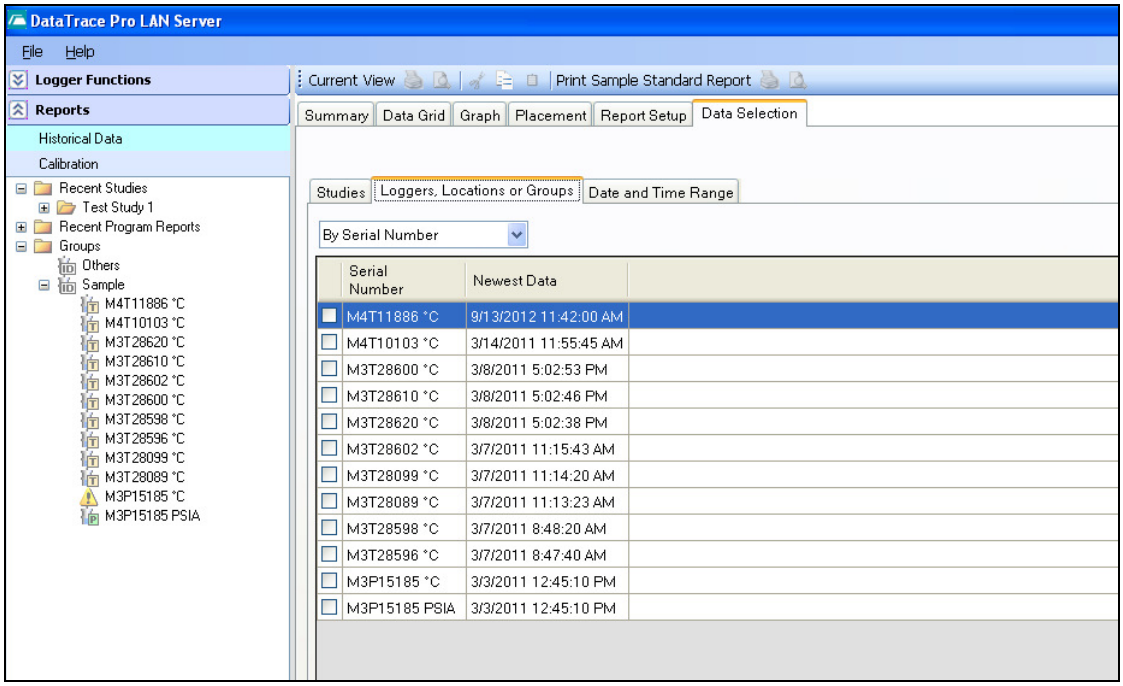
An additional check box is available to **Include Data Marked as Undesired** (see the bottom of the window in the previous screenshot). See Section 8.4.10: Data Control Methods for details. *This check box is available for all data selection modes.*

8.2.2 Select by Logger, Location or Group

Setting a Date and Time range will be required before the Get Data button will be enabled.

- Using the left side drop-down, loggers can be selected by Serial Number, Tag ID or by Group.
- The available selections can be limited to specific data types (e.g. temperature only or RH only) using the right side drop-down.

Note: The data from dual channel loggers (e.g. pressure and temperature logger) is treated as distinct. The temperature logged by such a logger is not excluded from selection when Temperature only is chosen.

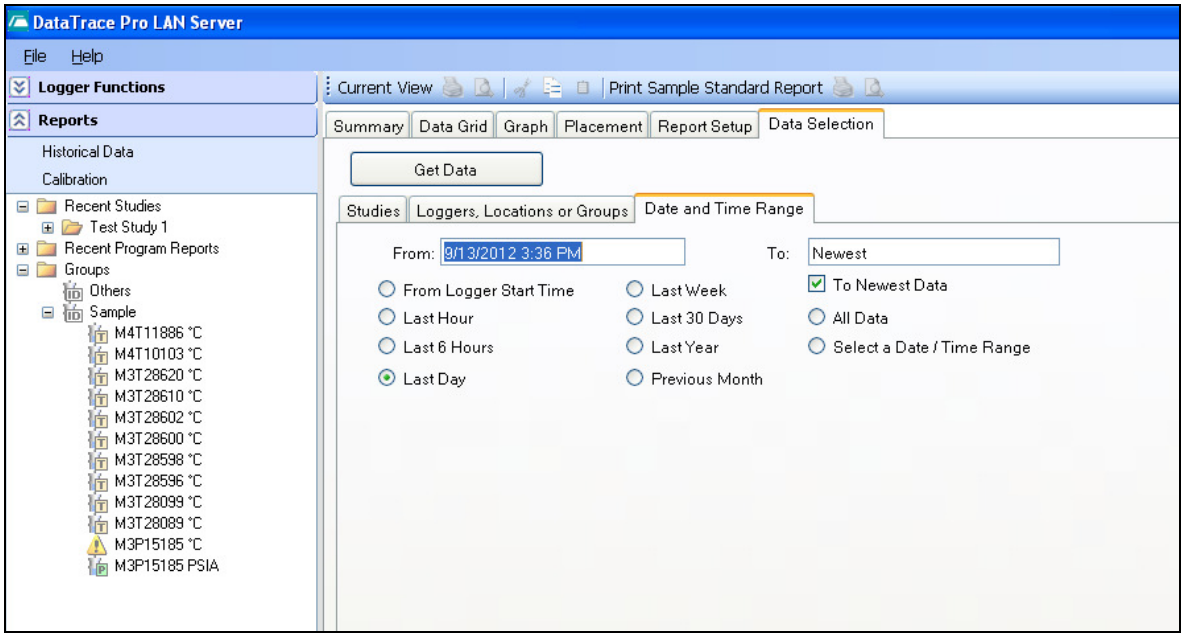


8.2.3 Setting the data Date and Time range

Selecting loggers will be required before the Get Data button will be enabled.

- Choose the starting time from the available standard ranges (e.g. **Last Day, Last Week, All Data**, et. al.) if desired
- If **Select a Data** / **Time Range** is chosen, manually set the date and time using the calendar (and time display) that will appear.
- If the **To Newest** check box is used, the data set will end with the most recent available data. If not checked, manually set the ending date and time using the calendar (and time display) that will appear.

Once both loggers and a date / time range have been selected, click the **Get Data** button located in the top left corner. The data will be retrieved and may be inspected using the standard views. The default display is a graph of the data. If an appropriate report template has been created, it can be selected from the Report Setup tab and printed or previewed using the upper right corner Print Report icons.



8.3 Viewing Data

After data selection, the data can be viewed or analyzed in four different ways: Summary, Data Grid, Graph, and Placement. Any one of these views can be individually printed (or previewed) using the icons located in the upper left hand corner. Within each view, options menus are available via right-clicking.

8.3.1 Summary

Master Summary

The top grid show the statistical summary for each type of data within the entire group: The minimum, maximum and average values, the spread (max. minus min.), The total number of data points, and which logger had the maximum, which had the minimum, and when these occurred.

Logger Summary

The bottom grid show statistics for the individual channels of each logger: The displayed values are the same as for the master summary, and also include Run ID, data logging interval, calculation results (e.g. final lethality Fo value or MKT average value) and factory calibration date.

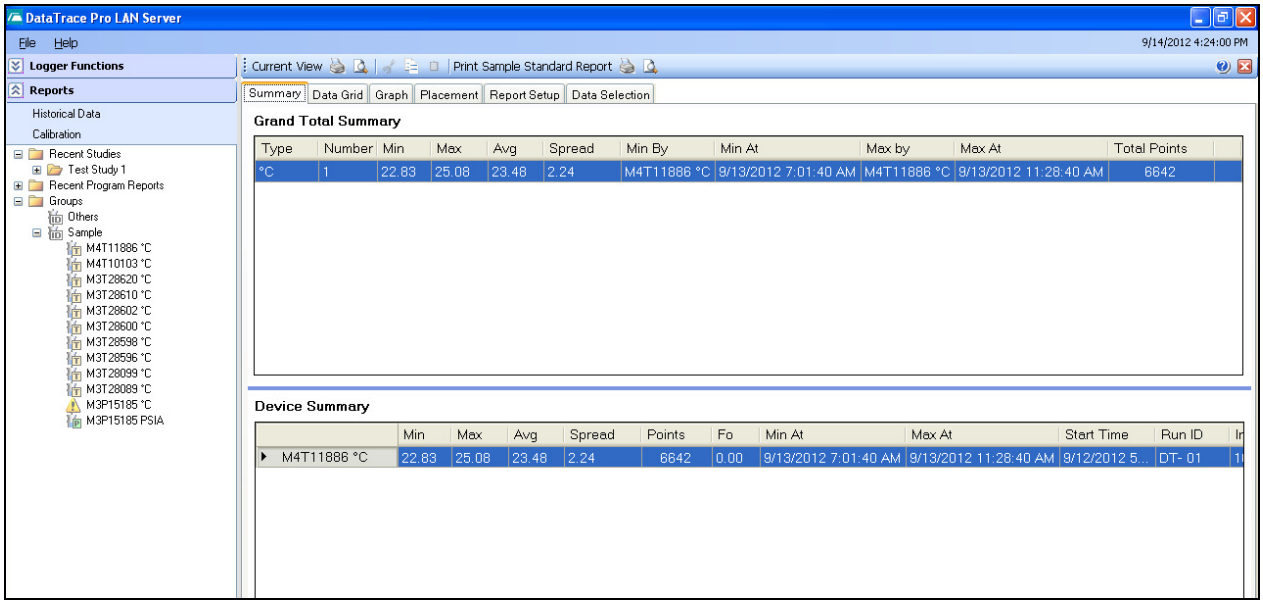
Sub-Summaries

A subset of data is referred to as a Phase. The data associated with a phase can also be summarized independently. See Section 8.4.7: Creating Phases for details.

User Comments: If data selection was via a study, the comment column in the logger summary grid shows any comments made when the logger was programmed or read. The comment can be edited (or a new one entered) by clicking on the comment column. Comments are stored in studies for each logger. If data access was not via 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 logger). *Comments are not printed as part of the summary printout. They may be included in a report as part of the cover page)*

Notes:

- *The summary page may be printed or previewed using the Current View print icons located in the upper left corner.*
- *The summary page may be included in a report (Report Setup > Item Selection > Data Summary*

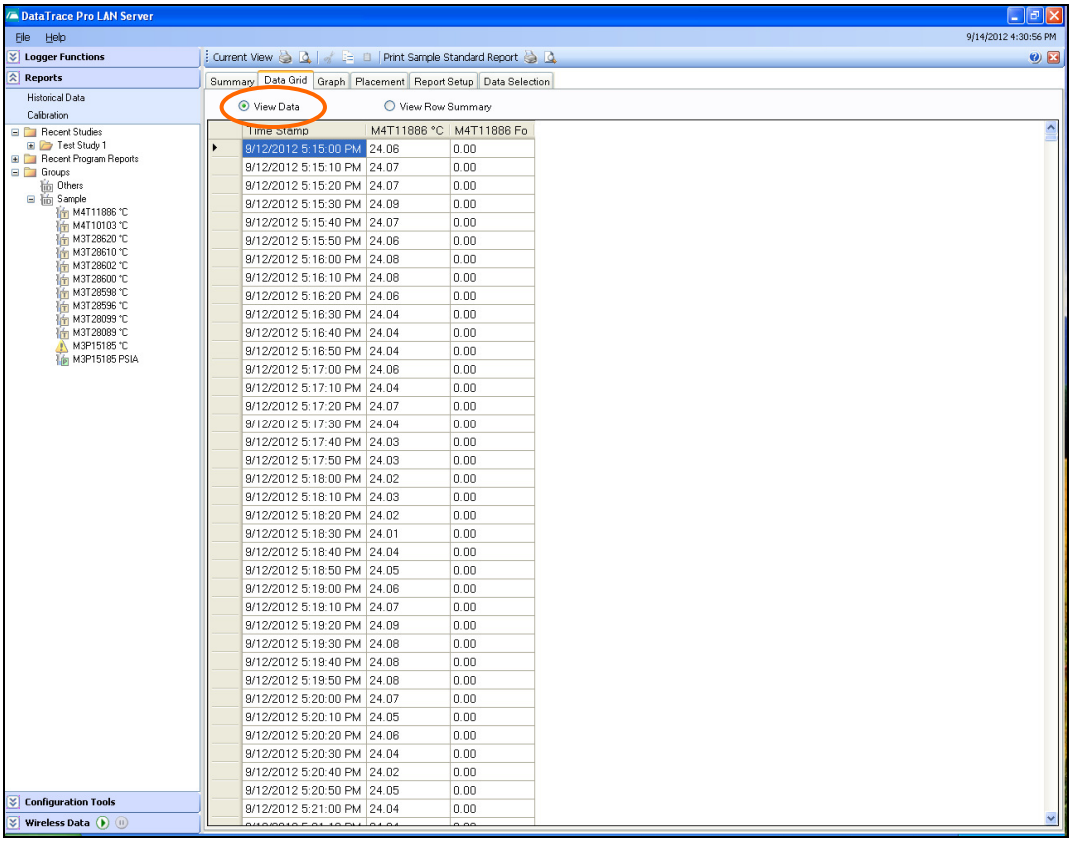


8.3.2 Data Grid

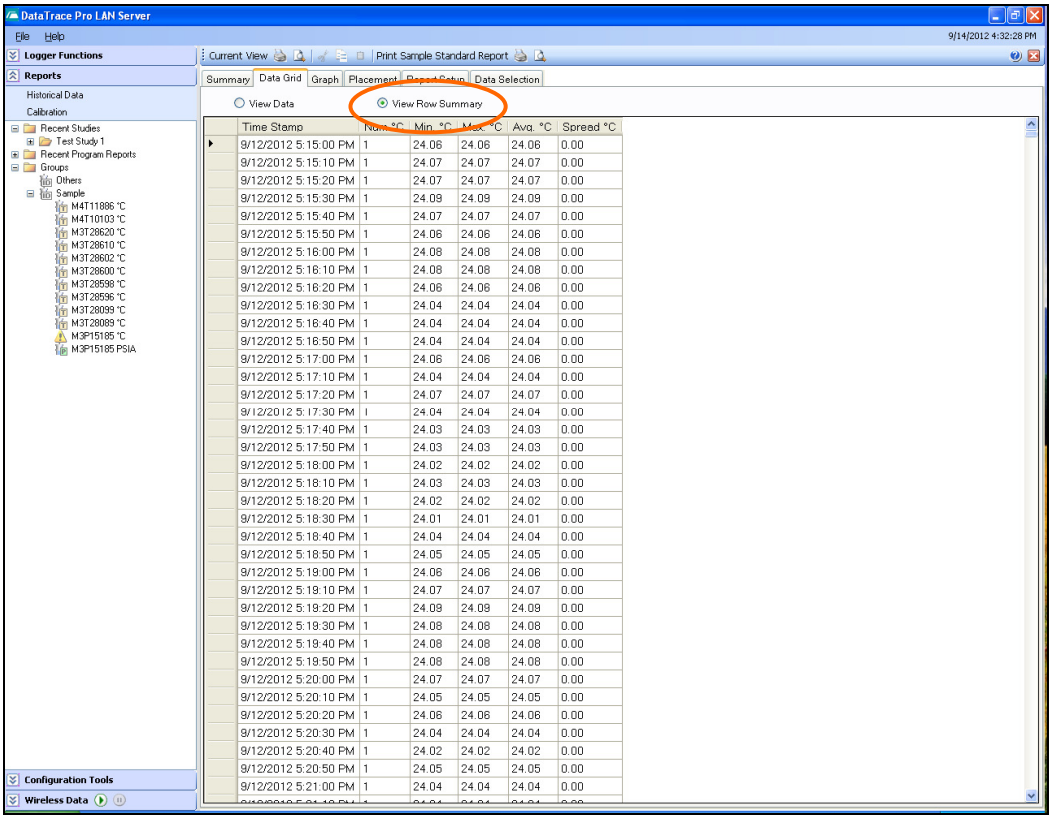
The data grid displays the data time-stamp, values, row summaries and calculations according to the following options. Right click on the grid to see its options menu. In the many sections below, we will cover the different menu options that are available through the right-click menu of the data grid.

Row Data or Row Summary view

- The **View Data** options is used to display the actual data values



- The **View Row Summary** options displays minimum, maximum average and spread of same data type at the given row time-stamp.



Data Exclusion by row or column

- If a row or rows are selected, they can be hidden or excluded. Hidden rows are not included in summaries nor displayed on the graph. 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 that you wish to exclude. Then right-click on the highlighted row(s) and then select Exclude Rows from the options menu.
- If a column or columns (loggers) are selected, they may be excluded. 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 that you wish to exclude. Then right-click on the highlighted column(s) and then select Exclude Columns from the options menu.
- Excluded data is not deleted; they are data that will not be included in the current report data set. In order to recover excluded data, the user must execute the data selection process again.
- To temporary hide data row(s), select the row(s) of interest, then right-click to show the options menu. Then select “Hide Selected Rows” option to hide them.
- Temporarily hidden data may be shown again using the “Show All Rows” menu item. The “Show All Rows” function does not work on excluded data.

Notes:

- *Data manipulations such as excluding rows or columns (loggers) are recorded in the report audit trail; this activity log should be included in reports intended to comply with 21 CFR Part 11 or similar regulations (Report Setup > Item Selection > Security Summary).*

- *If there are defined phases, the phase name will appear adjacent to the time-stamp.*
- *The numerical and date time formats of the displayed data are specified in Configuration Tools > System Setup.*

Data Deletion or Marking as Undesired

- Data Deletion permanently deletes the selected rows, columns or individual cells from the database.
- The “Mark this Data as Undesired” option tags the data so that it will no longer be normally available, but may still be viewed if the "Include data marked as undesired" option is enabled when first selecting data.
- Data deletion or marking is restricted to system administrators only
- Data deletion using the grid or graph menu may be completely prohibited in the system setup, in which case the menu item will not be available. See Section 2.2.1: Data Limits, Exception and Deletion Options for details.

Notes:

- *All data deletion or marking events are logged in the audit trail. When used, an option is provided to enter a comment or explanation for the action.*

Phase (Sub-Summary) control

The options menu contains many items to control phases. A phase is a defined time range within the data set upon which statistical summary, graphs or other data evaluations can be performed. Phases may be nested (i.e. a unique phase can be declared without regard to the bound of any other phases).

- Insert New Phase option: A phase (sub-summary for a report) may be defined by selecting rows and clicking this item.
- A phase may be defined by selecting starting and ending rows.
- Phases can be saved, and saved phases can be inserted into the data set.
- Individual phases or all phases can be removed.

Phase Saving Options

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 phase saving option defines what the reference time will be.

- **Elapsed Time:** The reference time will be the start of the data. If for example, a phase has been declared that starts 17 minutes after the start of data, when the saved phase is inserted into a new and different data set, it will also begin 17 minutes after the time of the first data point.
- **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. If for example, 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 may be either a high or a low value (e.g. -15), directionality (> or < logic) is presumed relative to the very first data measurement.
- **Temperature Maximum:** Similar to temperature set point, but the reference for elapsed time will be the time at which the maximum temperature was observed in the data set.
- **Temperature Minimum:** same logic as temperature maximum.

Display of Calculations

- **Reset Lethality:** Use this if it is desired to reset the lethality calculation back to zero (e.g. if the data set contains two or more distinct autoclave cycles). Click on a data row, and then this item. Accumulated Lethality will begin at zero starting at the time of the clicked data point. The Remove Lethality Reset item disables the reset point. This functionality is also available within the graph control menu.

- **Reference Logger(s)**: If calculations are enabled which require a specific logger be selected as a reference, the menu will contain an item for this selection when an entire column (specific to one logger) has been selected.
- **Enable** / **Disable calculation**: Allows for calculations normally applied to all loggers of the same data type to be disabled or enabled on an individual logger basis. The menu item for this is available only when an entire column (specific to one logger) has been selected.
  Calculations can be printed on separate pages if desired (Report Setup > Report Manager > Advanced Preferences).

Miscellaneous

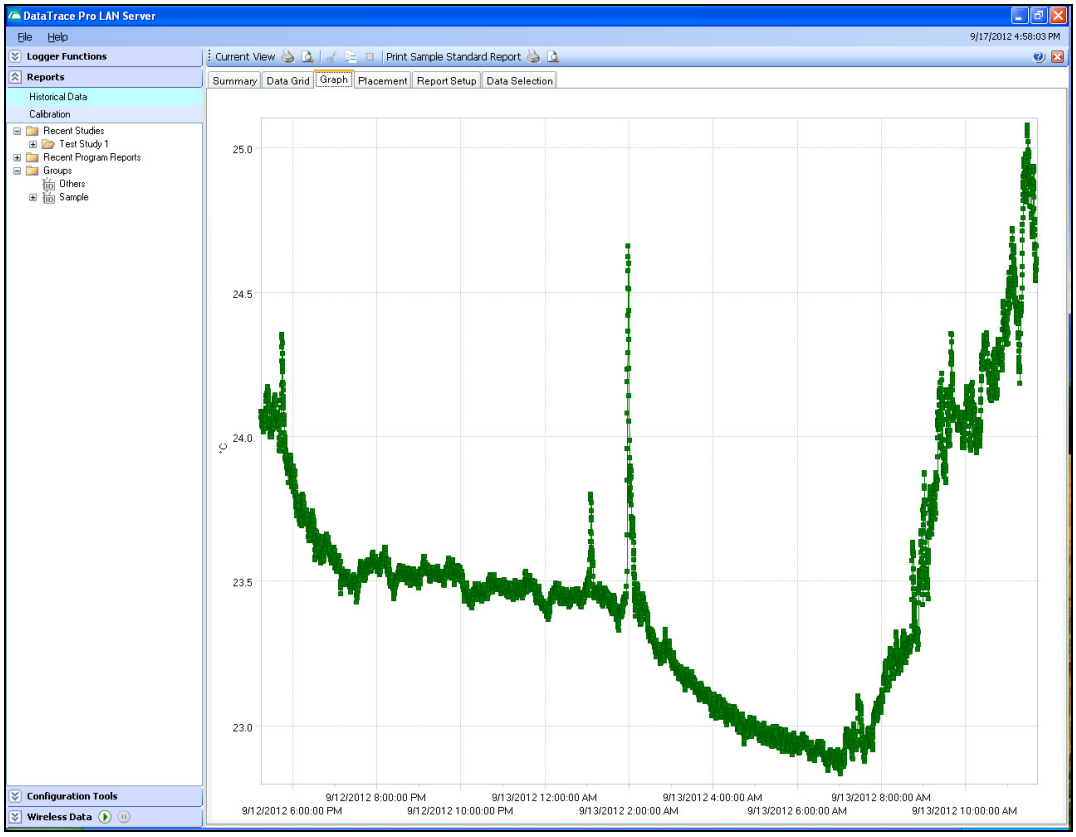
- **Increase Interval:** Allows the interval to be reduced for the selected rows (similar to the Increase Interval menu item in the graph.
- **Time Sliding:** Available only when data was accessed in elapsed time mode; allows data within a column to be shifted up or down in time.

Notes:

- *The current view of the data grid may be printed or previewed using the Current View print icons located in the upper left corner.*
- *The data grid, either standard or row summary view, with or without calculations may be included in a report (Report Setup > Item Selection)*

8.3.3 Graph

The graph view displays data in an XY graphical format with time on the X axis. The graph may be customized in various ways, and through its options menu provides access to more advanced functions such as phase creation or interval manipulation. The graph options menu is exposed by right clicking on the graph.



Plot, Zoom, and Axis scales

- **Zoom**: drag over the graph with mouse left button held down to highlight an area of interest and zoom in on it. Use the menu to **un-zoom** or refresh. While zoomed, scrolling sliders for each axis will be available.
- **Plot:** Set what data will be plotted (or not).
- **2nd Y Plot:** Set which data type will be scaled to the second (right side) axis.
- **Axis Limits**: Set auto scale or manually define minimum and maximum scale values for each graph axis.

Legend, Labeling and Line Colors

- **Use markers**: determines if plot markers are used
- **Hide legend:** The graph may be displayed with or without a legend.
- **Advanced**: Set legend text (options are Serial Number, Tag ID or Run ID), Line Colors, or specify a Graph Title.

Notes:

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

Custom Labels, Arrows, and Set-Point Limits

- Labels (custom text), arrows and limit lines may be added to the graph using the option menu "Labeling" items.
- Labels are inserted at the point of the last left click of the mouse prior to accessing the "Add Label to Graph" item.
- "Set Arrow Start" and "Set Arrow End" (arrow-head is at end) menu items allow the placement of arrows in the graph display area.
- Labels and Arrows are created with scale relative XY coordinates; relative positions are constant relative to zooming, labels or arrows may be defined while the graph is zoomed.
- "High Setpoint" and "Low Setpoint" menu items create horizontal lines that are defined relative to the Y axis. Low set point line is plotted in blue and high set point line in red.
- All labels or arrows may be removed using the options menu.
- Individual Labels, Arrows and Limit lines may be selected and moved, dragged or otherwise re-positioned using the mouse. Once selected, they may be removed using the Delete key.

Notes:

- *If one or more loggers have defined alarms, these may be displayed automatically on the graph (Report Setup > Report Manager > Advanced Preferences).*

Phase Creation (sub-summaries) and Control

A phase is a subset of the data with its own start time, end time and name. A phase is also a sub-summary. Phases can be created either from the Graph or the Data Grid.

1. Zoom in on or close to the desired data range.
2. From the graph options menu, select Summary Phase > Insert New Phase.
3. Enter a phase name when prompted (or accept default name).
4. The Phase Adjustment tool-bar will appear. Select Phase start and/or phase end and use the move buttons (right or left arrows) to adjust the phase start and end times. You can zoom to the starting or ending area of interest for precise control.
5. The vertical Phase marker lines may be dragged and dropped as desired.
6. Close the Phase Adjustment tool-bar when finished (click on small red close icon).

Additional Methods:

- A phase can be inserted to match an autoclave dwell cycle (plateau). The method used in conformance with European standards (NF EN 554) where the start and end of the phase occur at equal temperatures, and also equal to the minimum temperature between the start and end. It is preferable to zoom the graph in to something close tot he dwell cycle; and, this

is required if there are more than one plateaus within the data set. The dwell portion of data must be at least 5 degrees hotter than the surrounding data.

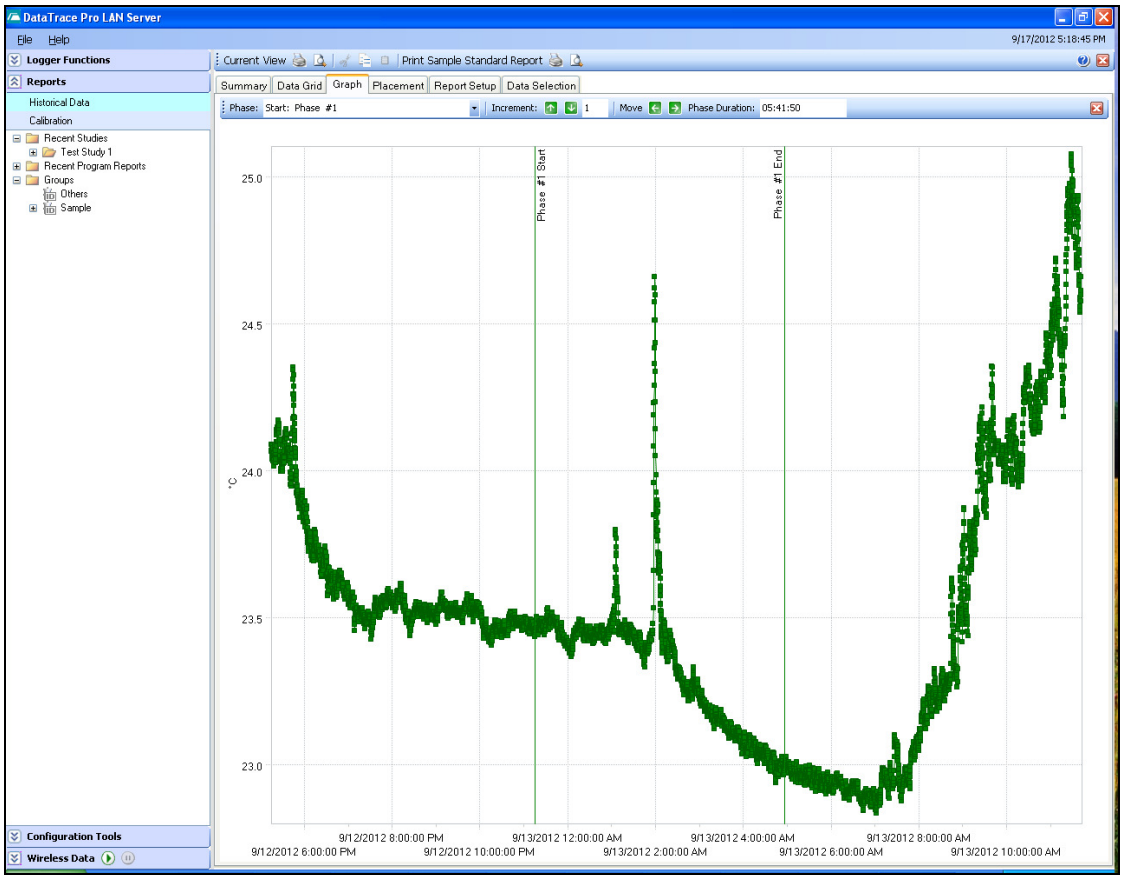
- If a phase or phases have been previously saved, they can be inserted into the existing data set. Phase insertion and saving options are discussed in Section 8.3.2 Data Grid; phases can also be declared and controlled from the data grid.
- If Low or High Set point limits have been defined, a menu item will be visible to allow a phase to be inserted to coincide with the set-point deviation. Phase timing is evaluated relative to data that is plotted on the Y axis only.

Additional Options:

- The phase labels (vertical lines, horizontal arrow, and phase name) may be optionally hidden.
- The phase name may optionally be displayed near the bottom or near the top of the graph.
- The Phase Adjustment tool-bar can be opened using the Adjust Phase menu item. Take care to select the appropriate phase start or end when multiple phases have been defined.
- The "Zoom to Phase" menu item, when selected, will instantly zoom the graph to the selected phase. In addition, the Summary Data view will be refreshed for the phase data only. *Un-zoom / Refresh the graph to restore the summary calculation to the standard "entire" data set.*

Notes:

- *Defined Phase names will appear in the Data Grid view adjacent to the time-stamp column.*
- *Phase duration is displayed in the Phase Adjustment tool-bar and can be used to accurately quantify the duration of various process events. Phase duration also will appear on Report Phase summaries.*
- *When a Phase summary is generated, all calculations are also performed. Lethality calculations will generally be more useful when limited to a phase range.*
- *Phase timing can also be adjusted by dragging and dropping phase lines as desired.*



Data Options

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

- **Create Study**: Enter a study name when prompted. A study will be created for the current loggers and zoomed data range. Repeat as desired in order to create sub-sets of the data for later individual processing. *See also: Section 8.4.9.1: Creating Studies.*
- **ReCalc Summary**: The Summary View will display statistics only be for the zoomed time range. Note: the summary is not limited to only those points visible on the graph! *Un-zoom / Refresh the graph to restore the summary calculation to the standard "entire" data set.*
- **Set Data Range to Match:** All data not currently visible will be excluded.
- **Exclude this data:** The data currently visible (zoom time range) will be excluded.
- **Mark Data as Undesired:** The data currently visible (zoom time range) will be excluded from the current data set and tagged within the database so that it will only be available if specifically requested ("Include data marked as undesired" data selection option). *Restricted to the Admin or Power User permission levels.*
- **Delete this data.** The data currently visible (zoom time range) will be excluded from the current data set and deleted from the database. *Restricted to the Admin permission level only, visible only if allowed by the system setup.*
- **Groups:** If the loggers being viewed belong to different groups (*see* Section 4.1 Managing Groups and Tags), use this to temporarily view only the selected group. Summary information will also be only for the selected group. Click "All Loggers" to return to the standard view. *This item is not visible if the 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.*
- **Reset Lethality:** Use this if it is desired to reset the lethality calculation back to zero (e.g. if the data set contains two or more distinct autoclave cycles). Click on a data point in the graph, and then this item. Accumulated Lethality will begin at zero starting at the time of the clicked data point. The Remove Lethality Resets disables all reset points. This functionality is also available within the data grid control menu.
  Data exclusion, deletion or marking as undesired is recorded in the report audit trail; this activity log should be included in reports intended to comply with 21 CFR Part 11 or similar regulations (Report Setup > Item Selection > Security Summary). Data deletion or marking as undesired is also recorded in the system audit trail with the opportunity to comment or explain the action. Reasons for data exclusions of any type may also be entered in the report comment if desired.

Notes:

- *Study creation and data deletion are audited events at both system and report levels. A digital signature may be required.*
- *Excluded data is not deleted; it is data that will not be included in the current report data set. In order to recover excluded data, the user must use the data selection process again. See Section 8.4.10: Data Control Methods for other exclusion, marking as undesired or data deletion details.*

Time Sliding

- The Time Sliding menu item exposes a tool-bar which allows the user to select a logger and move its data left or right on the graph (earlier or later in time) relative to the other loggers.
- The time sliding tool will be available only when data was selected by study and by individual logger, with the Use Elapsed Time option checked. *See Section 8.2 Selecting Data.*

Notes:

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

Increment Interval

Within a region of data, the data interval may be reduced by excluding alternating (or more) rows of data (in the data grid) such the remaining rows conform to the desired data interval.

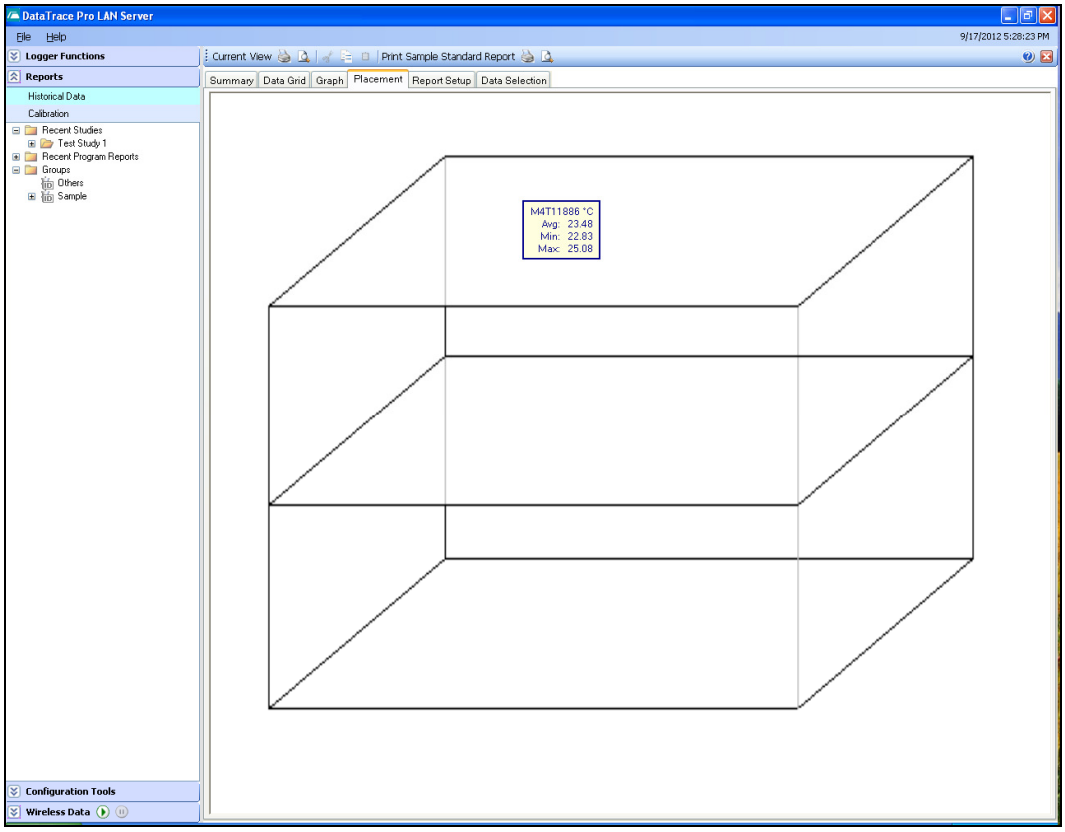
- Zoom in on the desired region.
- Access the graph options menu Increment Interval item, select the desired data interval.
- For precision, declare a phase, zoom to it and then set the data interval.
- Multiple and different data interval ranges are allowed.
- Rows which define the beginning or end of a phase, or a lethality reset, will not be excluded.

Notes:

- *Interval reduction can result in the inadvertent omissions when mixed data logging intervals exist.*
- *The current view of the graph may be printed or previewed using the Current View print icons located in the upper left corner.*
- *A graph of all of the data or of phase ranges may be included in a report (Report Setup > Item Selection)*

8.3.4 Placement

The Placement view allows information from or about individual loggers to be placed in specific locations relative to a background image. The placement view is controlled by its option menu which is access by right clicking on the display area.



Background Image

Use the menu items to import an image, change the image or clear it. The supported image file types are .bmp, .jpg and .gif. The background image is associated with the current report and will appear when this report is selected. Different background images may be associated with other reports.

Logger Placement

A text box is associated with each logger. It may be moved by dragging it to a desired location (place mouse cursor on the box, hold left mouse button down and move it as desired). It is initially convenient

to use the Auto-Arrange devices so as to lay out the boxes in an orderly fashion. Logger location is stored by serial number. The initial placement location for a logger (for future reports) will be the same regardless of the selected report.

Device Display Options

The information displayed will always contain either the logger's Serial Number or Tag ID (depending on the logger identification preference set for the report). Additional information may be displayed based on the selections: Last Value, Average, Minimum, Maximum, Spread, Calculation Result or Run ID

Notes:

- *The current placement view may be printed or previewed using the Current View print icons located in the upper left corner.*
- *The placement view may be included in a report (Report Setup > Item Selection)*

8.4 Creating Reports

When DataTrace Pro is installed, several default (or sample) report templates are provided. These may be deleted, modified, or used as the basis for a new template. The user should review the settings of a template prior to use. The default Report Templates and what they are intended to demonstrate are:

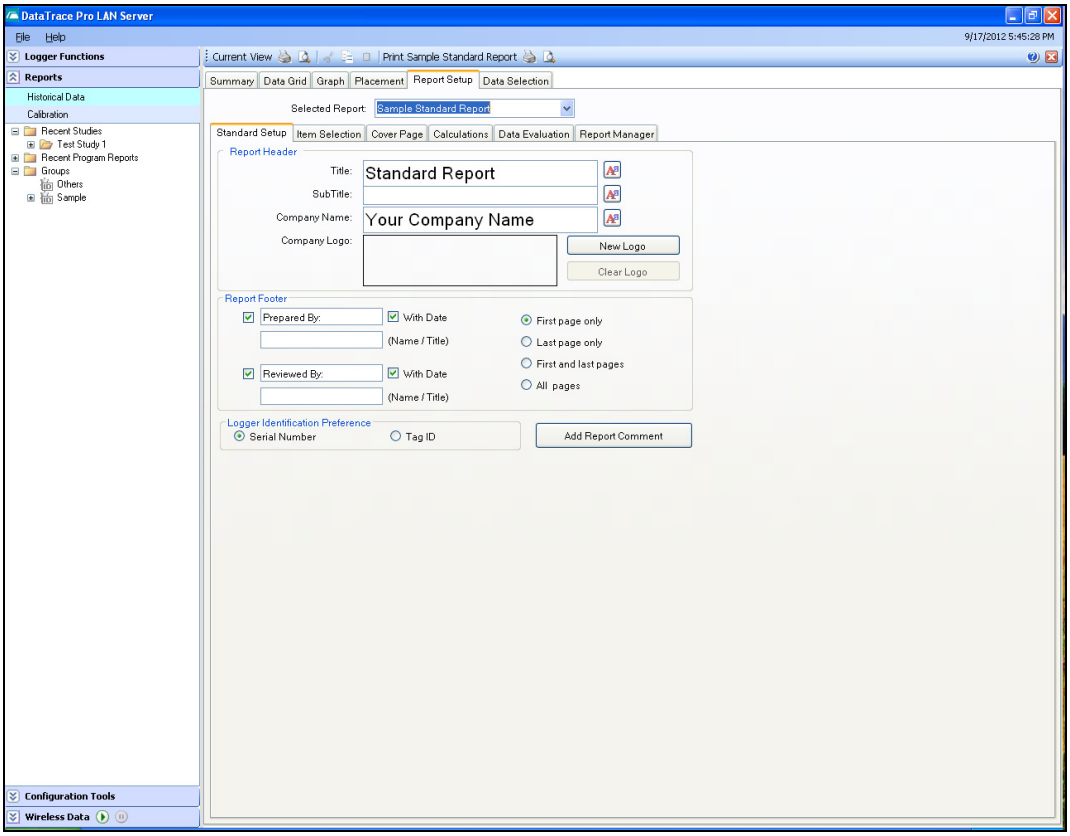
- Standard Report: logged data, summary and graph
- Autoclave Validation (Temperature Only): includes an Fo lethality calculation, simple pass / fail evaluation and attaches calibration reports. Data evaluation includes an example of equilibrium analysis, demonstrates usage of auto-phase insertion.
- Warehouse Stability Study: includes the Placement view
- Multiple Process Evaluation Report: includes placement, compressed data graph and is typically accessed by group and time range

  Note: demo studies and data sets are also included. A report cover page may contain a reference to a particular study. Observing the effects of various settings will be facilitated by using the referenced study.

A Report Template is a “blank” report which consists of a series of user-defined pages. The user may create and name as many report templates as desired. Any or all of the four standard views can be included in a report. Data can be printed as logged, condensed or otherwise manipulated (within regulatory or security constraints). Many other additional items (e.g. a cover page, pass / fail evaluation, Phase sub-summaries, logger calibration reports) may also be included.

Note:

- V*iewing data and printing reports does not require special permissions. Creating or modifying a report template requires Admin or Power User permission level.*



A Report Template is defined from within the Report Setup tab of the Data View window. The details are:

- Report Manager: Create or delete templates; select from various advanced preferences.
- Standard Setup: Define title, subtitle, company name, logo, signature line options, page layout, logger identification preference (Serial Number vs. Tag ID).
- Report Items: Choose the individual standard items to be included in the report; define phase handling and data compression. Add additional items to the report: Data Evaluation, Calibration reports, Programming Reports, Security summary (audit trail items about the loggers and how data was selected and manipulated), Alarms summary.
- Cover Page: Define Cover Page Text; optionally require additional data entry when a report is printed. Add additional items (to the cover page): Pass / Fail result, Calculation Final value and/or comments, Logger description, Logger factory calibration date, master (group) or logger summaries. The cover page will always contain basic information: Loggers in the report, Tag vs Serial Number, start time, interval and run ID.
- Calculations: Select which calculation (e.g. Lethality Fo) or calculations will be included in the report.
- Pass / Fail Evaluation: Define logical parameters and limits for the evaluation of the data set.
The user may manage or manipulate the data set using various methods. These methods apply only to what appears on the report; they in no way modify the underlying data. The methods are:
- Creating Phases: Using the graph to easily create a phase (sub-summary) or adjust its start and end times.
- Excluding Data: The various methods for excluding undesired or excess data from the current data set.
- Modifying Data Interval: Use the graph control to set different data print intervals within one or more ranges of the data set.
- Creating Studies: How to create one or more studies from a larger data set for subsequent individual processing.

Miscellaneous Report Types

- **Programming Report:** A report indicating which Loggers were programmed for a given start time and date. Accessed through various browser view options menus and "Recent Programming Reports" folders. May optionally be included as part of a data report.
- **Calibration Report:** A report on when Loggers were calibrated and the calibration results. Accessed through various browser view options menus and "Calibration Reports" folders. May optionally be included as part of a data report.
- **Environmental Reports**: Simple data history with minimum, maximum and average statistics for a predefined time range with alarm summary. Accessed through the Real Time radio data view.
- **System Configuration Report:** A report summarizing the entire system configuration (includes alarms, setup and security details). Accessed from the Configuration Tools options menu. Used for system validation or IQ/OQ/PQ documentation.
- **Report Template Summary**: A printout of the properties of a report template. Accessed from within the Data View window, at Report Setup > Report Manager tab. Used for report template validation or IQ/OQ/PQ documentation.
- **Audit Trail:** View or generate a report on system activity and usage. Accessed from the system Security Setup.
- **Diagnostic Report**: A report on the internal configuration of a logger. Accessed from the Test Logger window.
  Note: The program and calibration reports use the header and signature line options of the currently selected standard report; see Standard Setup.

Print and Page setup

From File menu (top left), access:

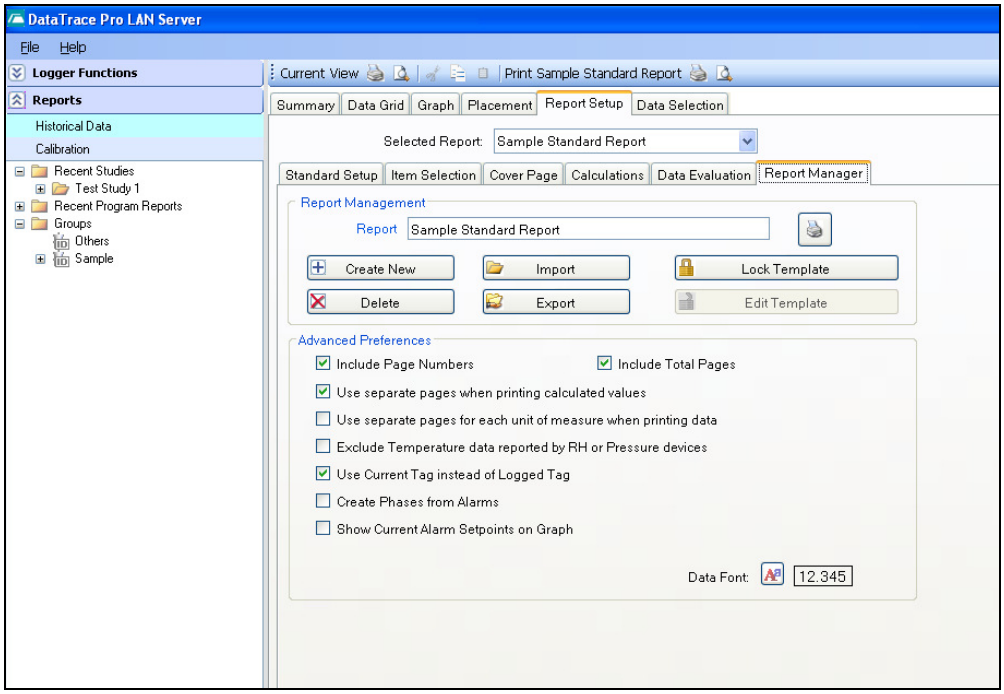
- Print Setup: Select which printer to use; other settings have no effect. DT Pro will print to the selected printer regardless of the Windows system default printer setting.
- Page Setup: Set print margins and page orientation (portrait or landscape); other settings have no effect. DT Pro will use the specified margins and layout regardless of the Windows system settings.

  Print to PDF: If you do not already have a PDF print driver (e.g. CutePDF, appears on the computer as an available printer), download one from the internet. Free ones are available. Using Print Setup, select the PDF printer.

Note: More advanced printer settings (e.g. paper size) are controlled by the Windows system printer settings specified through the Control Panel Printers window.

8.4.1 Report Manager:

The Report Manager tab is accessed from the Report Setup tab of the Data View window. The current report template is selected using the drop-down box.



Report Management

- **Report Name**: Edit the name of a report using the text box.
- **Create New**: A copy of the current report will be created. Edit the name of the report as desired. When creating a new template, it is best to start with the template that is closest to what is desired.
- **Delete**: The current (selected) report will be deleted. The operation is not allowed if there is only one report template.
- **Print Setup**: Generates a printout of all settings associated with the current report.
- **Import:** Create a new report template by importing a report template definition file (*.rpt).
- **Export**: Create and save a report template definition file (*.rpt).

Note: In a LAN environment, Report Template export is available only on the host computer (the physical location of the database).

Advanced Preferences

Most of the Advanced Preferences items are self-explanatory. The items are:

- **Include Page Numbers (and Total Pages):** Page numbering may be undesirable if second-party software is used to concatenate PDF files into larger or more complex reports.
- **Use separate pages when printing calculated values:** Lethality results can be printed on separate pages.
- **Use separate pages for each unit of measure when printing data:** Temperature and humidity data may be forced to print on separate pages.
- **Exclude temperature data reported by RH or Pressure devices:** The accuracy and response time of the temperature measurement of these devices is usually lower than temperature only loggers; therefore, it may be desirable to exclude this data.
- **Use Current Tag instead of Logged Tag:** Tag IDs are logged with data. If a Tag ID is changed or assigned after data logging has occurred, the newer Tag may be used for the report.
- **Create Phases from Alarms:** Creates a phase for any alarm events that occurred, where phase start and end will be the alarm start and end times.
- **Show current Alarm Setpoints on Graph:** Value alarm settings will be shown as horizontal limit lines on the graph.
- The **Data Font** button sets both font style and size for data grid printing.

- **Process data and graphs by Group**. If selected, and only if the loggers being processed belong to different user defined groups (*see Section 4.1 Managing Groups and Tags*), any selected data printouts, summaries or graphs will be generated for each distinct group. This option will only be available if there is more than one group available.

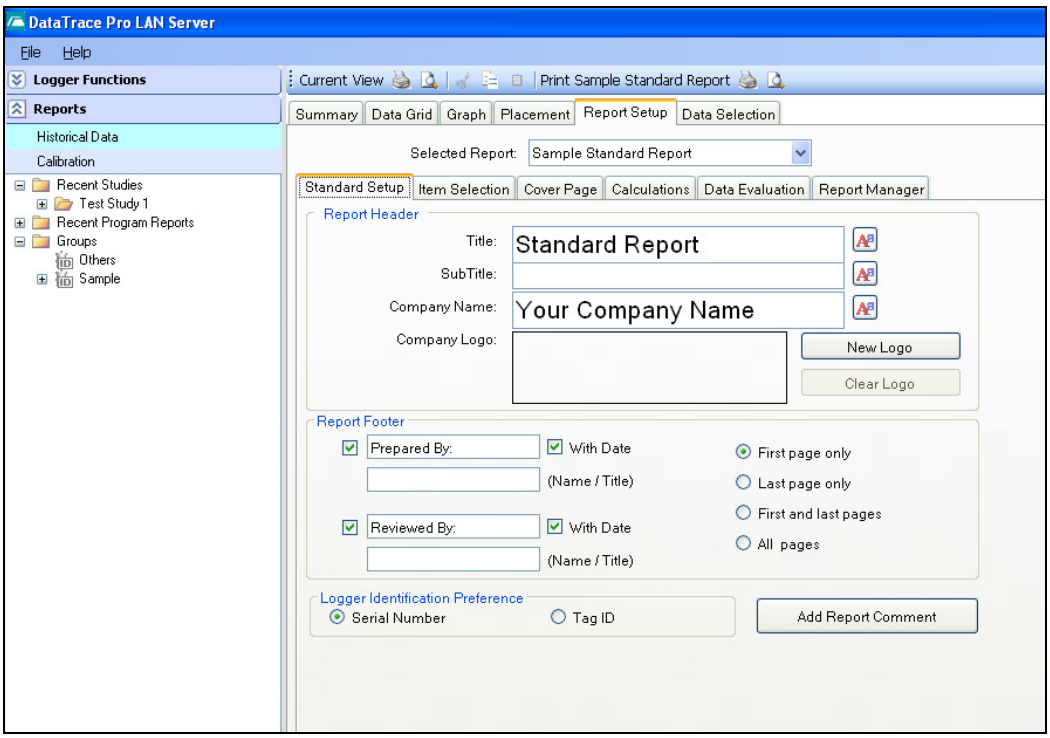
Report Template Validation

Use this button to print a description of the report template and all options defined for it.

8.4.2 Standard Setup:

The Report Standard Setup tab is accessed from the Report Setup tab of the Data View window. The current report template is selected using the drop-down box. Most items are self-explanatory.

***Page orientation** (portrait or landscape), **page margins** and **printers** can be set from the Page Setup or Print Setup items in the File menu.*



The following options apply to every page on the report:

Header Options

- **Title:** Set a title for the report (may be different than the report name)
- **Sub-Title**: Set a sub-title
- **Company Name:** Set your company name (if desired)
- **Company Logo:** Use the New or Clear logo buttons to import a logo image for the report.
- The Font buttons set both font style and size for the individual items.

Footer Options

- The footer options pertain to signature lines, dates and personal titles.
- Signature lines may be placed on only the first page, only the last, the first and last or all pages.
- One or two signature lines may be added (check mark in left most box)

- Each signature line may have a label. The default labels are "Prepared By:" and "Verified By:" These labels may be edited.
- Each signature line may have a date associated with it (use check box).
- A title may be printed below the signature line (enter personal title in the provided text box).

Logger Identification

- Set whether loggers are identified by serial number or by Tag ID. On the report cover page, both serial number and Tag ID are shown, on other pages, only the selected logger identification method will be used.

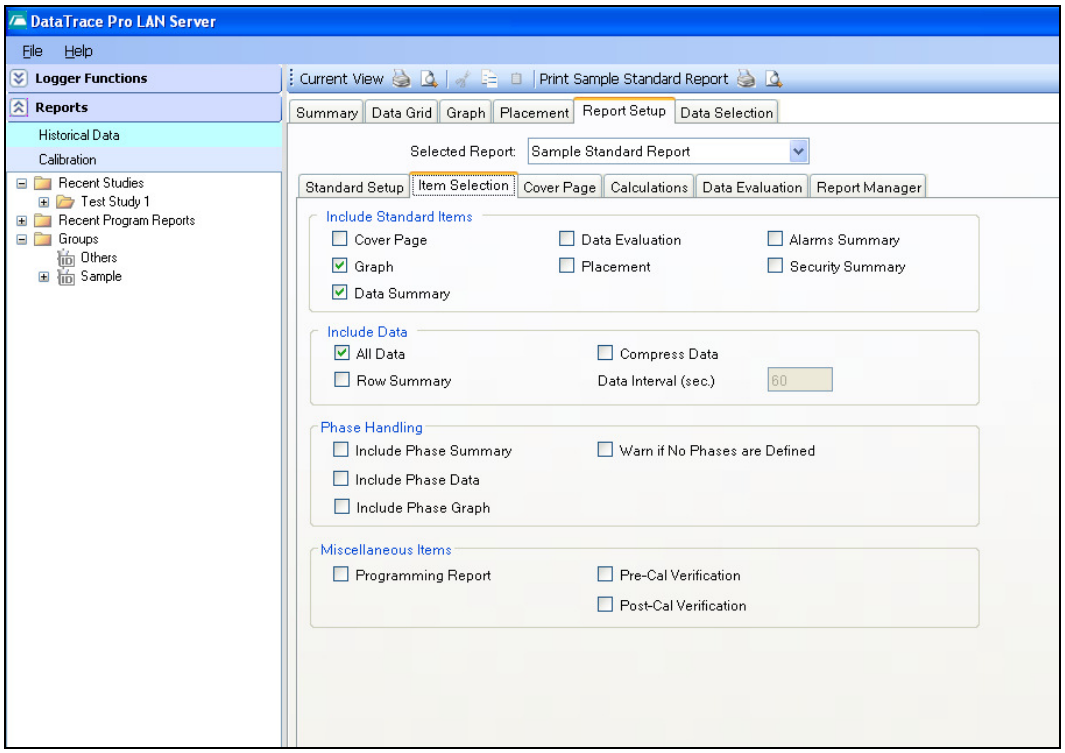
Add Report Comment (or image)

A comment or additional image file may be included in the report. There is no inherent limit to the length of text that may be included. IF desired, and image may be included (a typical image might be a scan of the printed tape output from an autoclave). Text comments or embedded images are not saved (they will exist only within the printed output of the report).

Note: The text and image processing capabilities of DT Pro are limited. It may be necessary to reduce image sizes using external tools. Within the comment input window, a button is provided to preview how the comment and / or image will appear on the report.

8.4.3 Report Items:

The Report Items tab is accessed from the Report Setup tab of the Data View window. The current report template is selected using the drop-down box. Most items are self-explanatory.



The Report Items tab is used to define what types of pages will be included in the report. Place a check mark in the items that are desired for the current report template.

Standard Items

- **Cover Page**: The first page of the report will be as defined in the Cover Page setup tab.

- **Graph**: A graph of the entire data set will be included as setup and or labeled in the Graph tab.
- **Data Summary**: A summary of the entire data set will be included as seen in the Summary tab.
- **Data Evaluation**: Pass / Fail results will be generated per the logical definitions set in the Data Evaluation tab.
- **Placement**: The placement image will be included as defined in the Placement tab.
- **Alarms Summary**: Includes a summary of all alarms (or none) that occurred during the data time range for the selected loggers.
- **Security Summary**: Includes a printout of the report audit trail: how data was selected, what data was excluded or otherwise manipulated, data security verification status, system audit trail and other items required to meet 21 CFR part 11 or similar regulations.

Data Printing Control

- **All Data:** includes a printout of the data grid standard view.
- **Row Summary:** includes a printout of the data grid row summary view.
- **Compress Data:** available only if one of the previous is selected. If selected, the data printout will be per the defined data interval (e.g. if data was logged at 10 second intervals, and compression of 1 minute is set, only one of every six data points would be printed). *The data interval unit (i.e. seconds, minutes or hours) is set in System Setup.*
  Note: Data compression can result in the inadvertent omissions when mixed data logging intervals exist.

Phase Handling

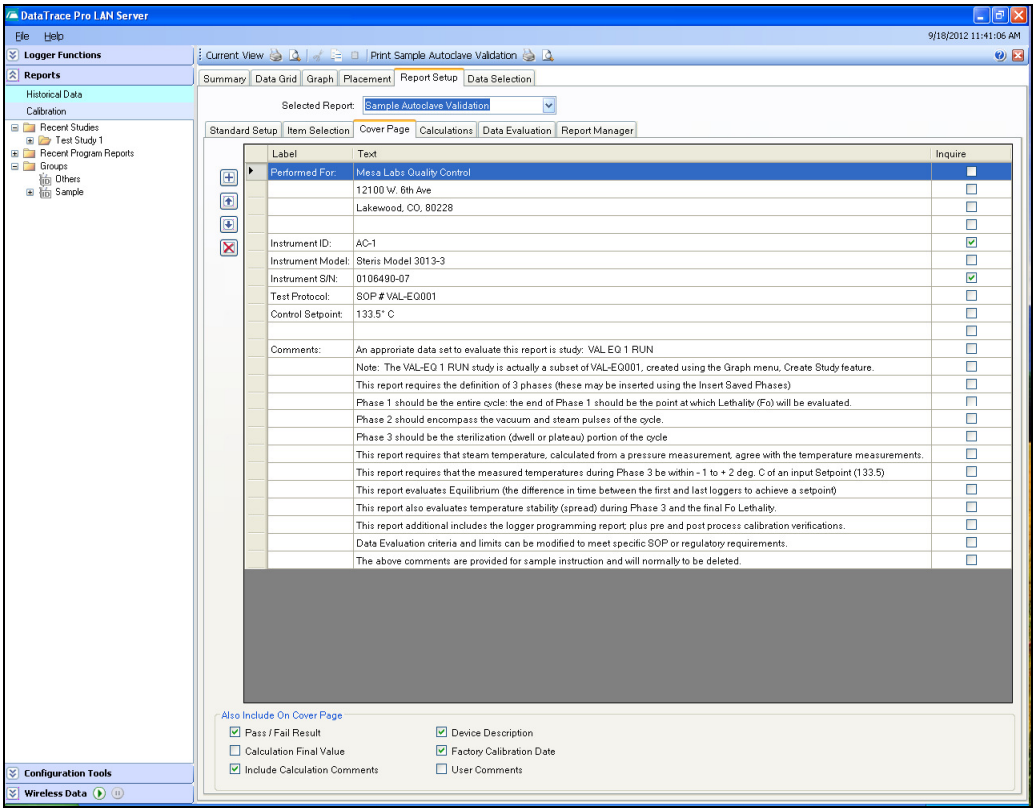
- **Include Phase Summary:** the summary statistics for each defined phase.
- **Include Phase Graph:** A graph zoomed in to each defined phase.
- **Include Phase Data:** The data for each defined phase; this data may also be compressed at the same or a different interval than that defined for All Data.
- **Warn if no Phases are defined:** Generates a warning message (with option to Cancel) if an attempt is made to print this report when no phases have been defined.

Miscellaneous Items

- **Programming Report:** include the programming detail report page.
- **Pre-Cal Verification**: include the most recent calibration reports for the selected loggers prior to the start of the current data set.
- **Post-Cal Verification**: include the most recent calibration reports for the selected loggers after the end of the current data set.

8.4.4 Cover Page:

The Cover Page tab is accessed from the Report Setup tab of the Data View window. The current report template is selected using the drop-down box. Most items are self-explanatory.



The Cover Page tab is used to define or customize the cover (first) page of report. The cover page may be previewed using the current view (upper left) print preview button.

Standard Items

The cover page will always contain a list of the loggers; the data start time, logging interval and Run ID.

User Defined Text

The cover page may contain additional user defined text. This text is defined by the rows of the cover page grid.

- Use the Add button to create a new row.
- Select a row and use the Delete button to remove it.
- Select a row and use the Up / Down arrow buttons to move that row relative to the others.
- In each row, enter either a label or text or both as desired.
- Create blank rows (no label or text) if additional spacing between items is desired.
- Inquire: if checked, data entry will be required when the report is printed or previewed (see Data Entry Inquiry below).

Notes:

- *The typical use for user defined text is to allow complete customization of the cover page. Typical items that might be included are: a client or department name, address or contact information, a test protocol, procedure or process name, test equipment calibration information, results or data from additional tests performed (e.g. stop watch timing of autoclave cycles), or comments about the test and deviations noted.*

Data Entry Inquiry

If one or more rows have the **Inquire** option checked, the following will happen when a cover page is printed or previewed. A data entry box will appear and request the user to enter data. The label specified for the row will be displayed, and the text (if any) will be the default input value. An inquiry will be made for each row which requires it.

Notes:

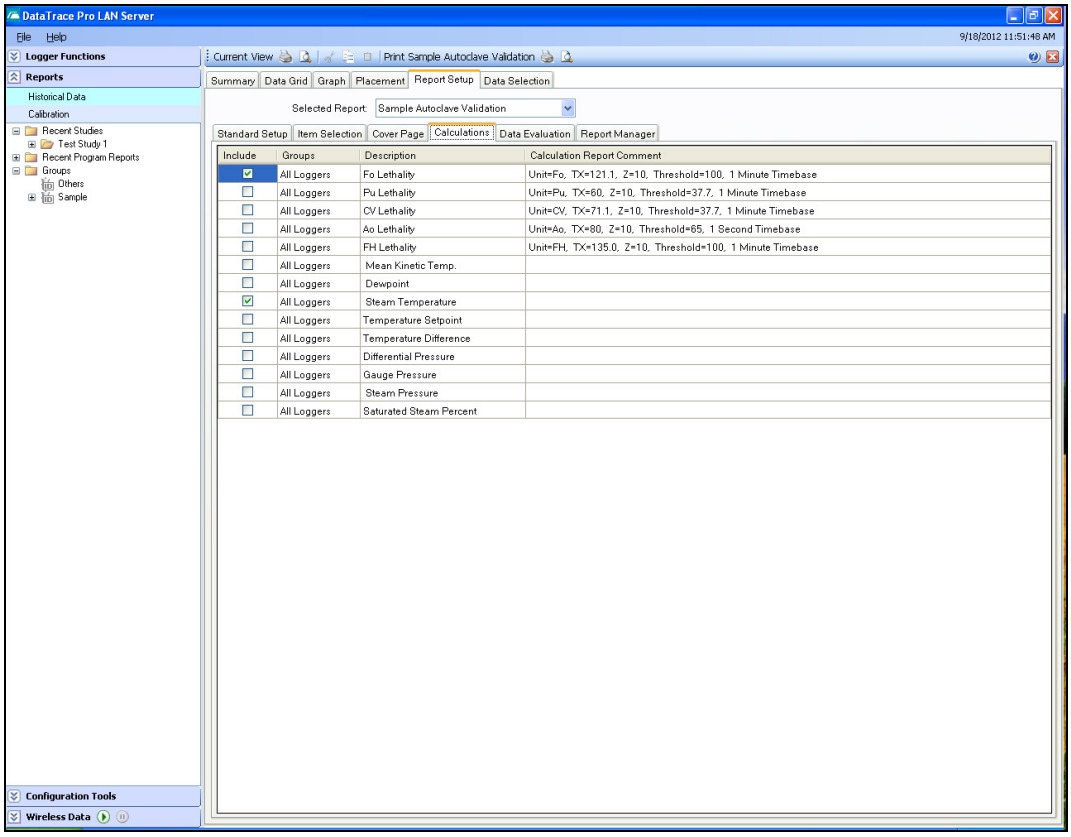
- *The typical use for data inquiry is to require the report user to enter information such as the ID of test equipment used, a protocol name, the vessel or autoclave under test, some other process identifier or additional test results.*

Additional Items

- **Pass / Fail result**: include the data evaluation result on the cover page.
- **Calculation Final Value**: applies only to calculations that produce a final value (e.g. MKT or a lethality calculation); calculation must also be specified in the Calculations tab.
- **Calculation Comments**: include any comments defined for the calculation(s) specified for the report. For a lethality calculation, the comment would typically by the values used for TX, Z and Threshold. Calculation parameters and comments are defined in System Setup
- **Device Description**: Include the serial number, Tag ID and description specified for the loggers in Device Configuration.
- **Factory Calibration Date**: Include the serial number, Tag ID and the date of factory calibration for the loggers. Serial Number and Tag ID will not be repeated if Device Description is also selected.
- **User Comments**: comments entered during the Programming or Reading of a logger will be included.

8.4.5 Calculations:

The Calculations tab is accessed from the Report Setup tab of the Data View window. The current report template is selected using the drop-down box.



The Calculations tab is used to define which calculations are to be included in the report template. The grid shows the available calculations and comments defined for that calculation.

Inclusion

- Use a check mark to indicate which calculation is desired

- More than one calculation may be included.
- The result of calculations that produce only a final value (e.g. Mean Kinetic Temperature) will be displayed in the summary view.
- The result of calculations that produce only columnar or row output (e.g. Dew point, Steam Temperature) will be displayed in the data grid view (unless the calculation has been hidden).
- The result of calculations that produce both (e.g. Lethality calculations) will be displayed in both views.
- The result of calculations that produce columnar outputs may optionally be plotted on the Graph.

See Section 2.4.1: Available Calculations for description of each individual calculation.

Once a calculation has been selected for a report, it will by default be performed for all loggers of the required data type. If it is desired that the calculation not be performed for one or more loggers, the calculation may be individually disabled in the data grid view. Select a column of logger data and right click to expose the grid menu. Calculations that are defined for this logger are shown, and may be checked or un-checked to enable or disable the calculation for that specific logger.

Comment Control

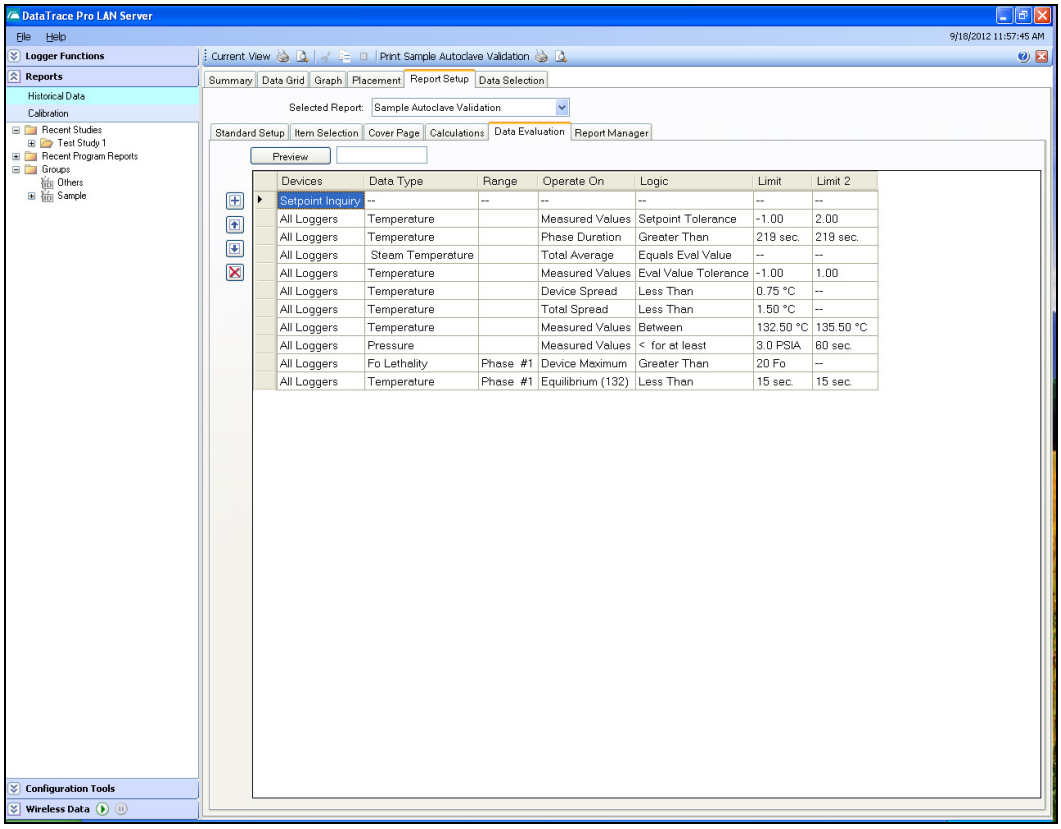
The calculation comments may be included on the Report Cover Page). For those calculations that have user defined parameters (e.g. Lethality TX, Z and Threshold), it is recommended the parameters be documented within the calculation comment for subsequent report inclusion.

Calculations Setup

The parameters, comments and units of measure (if applicable) for a calculation are set in the Calculations tab of System Setup. See Section 2.4.1: Available Calculations for details. *Access to calculation configuration is restricted to Admin or Power User permission levels.*

8.4.6 Pass/Fail Evaluation:

The Data Evaluation tab is accessed from the Report Setup tab of the Data View window. The current report template is selected using the drop-down box.



The Data Evaluation tab is used to define logical conditions that generate a Pass or Fail result for the data set (and the report). The conditions are defined within the rows of the evaluation grid. Each row is a test case which generates a Pass or Fail result. If all rows "Pass", the evaluation result is Pass, if a single row fails, a Fail condition is generated.

- It is best to have selected an appropriate data set prior to defining the logical conditions.
- The Preview button may be used to test the logic definition or obtain a preliminary Pass / Fail result.
- Data Evaluation is only included in a report if it is defined in Report Setup > Item Selection.
- The printed Data Evaluation page(s) include the individual row results.
  Data Evaluation occurs sequentially from the first row until the last row. Within each row, evaluation progresses per the definitions entered in each cell from left to right. The following items describe how to use the grid and the allowed selections for the columns. To select or edit an item, click on the grid cell.

Please review all logical selections prior to defining criteria; in some cases, item availability is dependant upon prior selections.

Row Control

- Use the Add button to create a new row.
- Select a row and use the Delete button to remove it.
- Select a row and use the Up / Down arrow buttons to move that row relative to the others.

Devices

Use this column to specify if the logic will be applied to all loggers, a specified group, or, select a specific logger (by serial number).

The menu for this column also allows for "**Setpoint Inquiry**", see Setpoint and Evaluation Values below. Once this type of row is selected, it cannot be changed (it must be deleted and a new row added if desired)

In general, "All loggers" is the preferred selection since the next item allows for data type differentiation.

Data Type

Use this column to specify a data type: Temperature, Humidity or Pressure. If a calculation is defined for the current report template, the calculation will also be an available type.

A typical use of calculation selection: autoclave validation criteria where Fo lethality final value must be in excess of a limit.

Range

Set the range of data to be evaluated. This may be all of the data, the first or last data point, a particular phase in the data, the last point in a phase, or the data encompassed by one or more phases.

When evaluating data sets with multiple phases, the order of phase declaration must coincide with the phase numbering (Phase 1, Phase 2...) assigned for data range (unless the logical operators to be applied to each phase are identical).

Operate On

Given all of the previously defined criteria, select which numbers or values are to be processed. The selections are:

- **Measured Values**: Process the actual logged data values.
- **Device Minimum, Maximum, Average or Spread:** process the summary values for the individual loggers (summary view "Device" lower grid).
- **Total Minimum, Maximum, Average or Spread**: process the summary values for the entire group (summary view "Master" upper grid).
- **Number of Loggers**: It can be required that the number of temperature loggers equal or exceed a limit.
- **Spread / Timestamp**: the spread between loggers at any one time (the spread column of the Row Summary data grid view).
- **Equilibrium**: The time difference between the first and last loggers of a group to achieve a set-point. Typically used in autoclave penetration studies.
- **Phase Duration**: The difference between the start and end time of a phase.
- **Interval**: It can be required that the data logging interval be equal that specified by procedures.
- **Setpoint**: If a set point inquiry row was previously defined (in rows above), that user entry can be evaluated.

Logic

Given all of the previously defined criteria, specify the logical operator that is to be applied to the numbers or values that are to be processed. The selections are:

- **Greater Than**: the value(s) must be greater than a limit
- **Less Than**: the value(s) must be less than a limit
- **Between**: the value(s) must be between to two limits (equal to the limit is a Fail condition)
- **Equa**l: the value(s) must equal a set-point
- **> for at Least**: the value(s) must be greater than a limit for a defined minimum amount of time.
- **< for at Least**: the value(s) must be less than a limit for a defined minimum amount of time.
- **> for no more than**: the value(s) may not exceed a limit for more than a defined amount of time.
- **< for no more than**: the value(s) may not be less than a limit for more than a defined amount of time.

Additional items refer to the declaration of a Set point or an Evaluation value, or a logic specification relative to one of these variables. See below for details.

Limits

These columns display the limit value or values. Click on a cell to edit the limit value.

Set Points and Evaluation Values

The Pass / Fail control allows the user to specify one or more set points or evaluation value variables; subsequent evaluation rows can be process logically relative to these variables. This allows any data to be statistically analyzed relative to either user input or any other statistical result (e.g. an average of some data type during a phase).

A Set point can be defined using the **Devices** column menu; an optional user prompt may be entered. When a report is generated, this row will cause the user to be prompted to enter a set point value, but this row will not generate a Pass or Fail condition.

A Set point or Evaluation value can also be defined from the output of the Devices, Range and Operate On definitions; suing the Logic column entry **"Equals Setpoint" or "Equal Eval Value"**. This could allow setting a evaluation value equal to the steam temperature calculated by a pressure logger during a particular defined phase. Setpoint or evaluation value declaration is only allowed when the **Operate On** column produces a single value (e.g. an average, maximum or minimum value).

Once a Setpoint or evaluation value have been established by prior row definitions, these variables can subsequently be used to evaluate data using the selections in the logic column. The available selections are:

- **Greater Than Setpoint**; the resulting value(s) must be greater than Set point for a Pass condition.
- **Less Than Setpoint**; the resulting value(s) must be less than Set point for a Pass condition.
- **Setpoint Tolerance**, the resulting value must be greater than Set point less a lower limit and less than Setpoint plus an upper limit. When selected, inquiries for the limits will occur.
- **Greater Than Eval Value**; the resulting value(s) must be greater than the Eval Value for a Pass condition.
- **Less Than Eval Value**; the resulting value(s) must be less than the Eval Value for a Pass condition.
- **Eval Value Tolerance**, the resulting value must be greater than the evaluation value less a lower limit and less than the evaluation value plus an upper limit. When selected, inquiries for the limits will occur.
  A most common usage of these features would be to allow input of the set point temperature of an autoclave, and subsequently evaluate the dwell portion of the data and require it be within limits of the set point. Other examples are:

  - If an evaluation value was previously set to be equal to the average steam temperature calculated by a pressure logger during a particular defined phase, a subsequent row could be defined to evaluate the average of measured temperature during the same phase relative to the steam temperature, within defined limits.
  - A set point inquiry row could request the user enter the results of a manual measurement or test, to be included in the report, and evaluated using the Operate On Setpoint selection and any desired logic limits.
  - Setting the Eval value within one phase of data, and subsequently comparing a different phase of data to the eval value allows for evaluation or process repeatability.
  - Setpoint inquiries could represent calibration reference values for the generation a calibration tolerances and pass fail conditions.

Caution: Setpoint and evaluation values are stored as numbers without units of measure. It therefore is possible to define somewhat illogical requirements (e.g. that the average humidity equal a temperature maximum).

Setpoint entries or and evaluation value assignments will be indicated on any printed report.

Multiple Setpoint inquiries or evaluation value definitions may be used; however, it is important to note that the order of declaration can affect the results. The evaluation order is from top to bottom. Row order can be changed by selecting and entire row and using the provided up and down arrows.

Usage

Given the options, it is possible to create Pass / Fail conditions which are a simple as requiring the group average to exceed a limit, to as complicated as a IEN compliant Autoclave validation including vacuum cycle pressure analysis with penetration study. The default report templates (at time of installation) contain examples of various types and degrees of complexity for data evaluation.

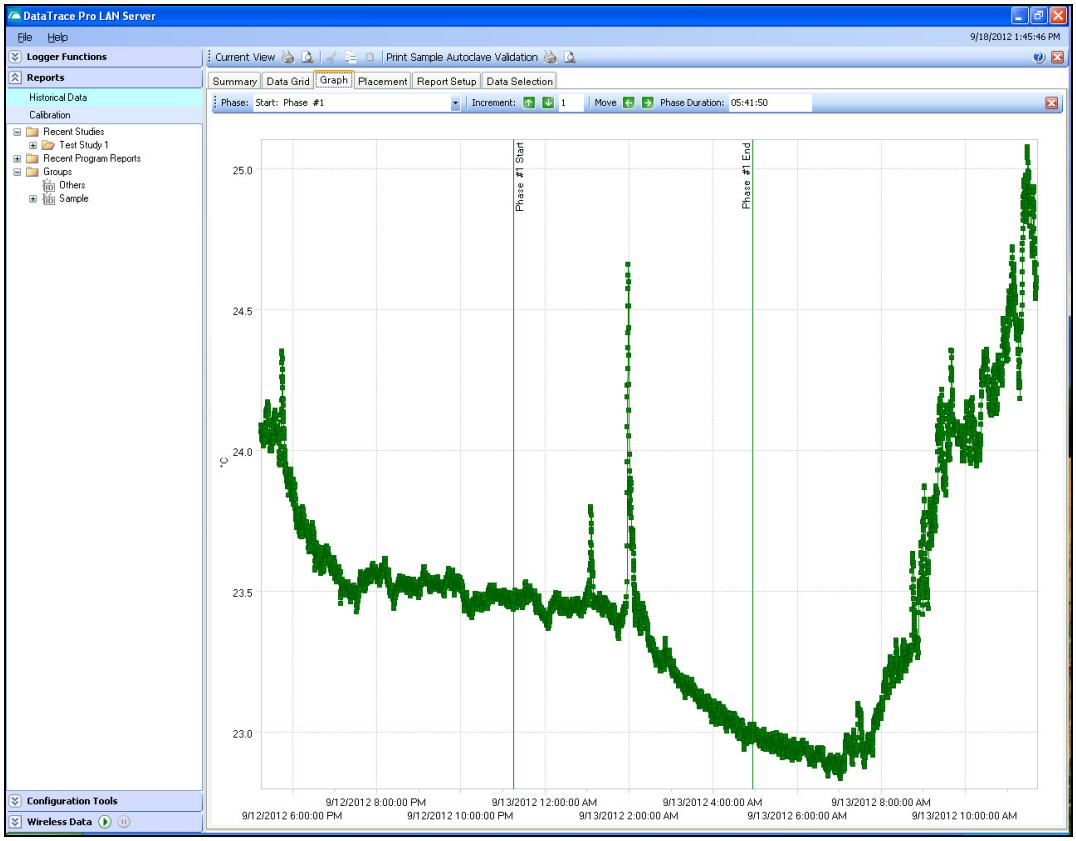
A preview button is provided for reviewing the pass fail declarations without generating a complete report.

Validation

The setup of data evaluation for each report template should be designed to conform to existing procedures (when possible). In a regulated environment, the setup should be documented, reviewed and approved (typically as part of IQ/OQ/PQ). Use the Report Template Validation button located in the Report Manager tab to print the data evaluation setup (and other report template parameters).

8.4.7 Creating Phases (Sub-summaries):

A phase is a subset of a data set with its own start time, end time and name. A phase also defines a time range for a sub-summary.



Phases are created from within the Data View window, using the Graph control options menu (accessed via a right click on the graph)

Phase Creation

1. Zoom in on or close to the desired data range.
2. From the graph options menu, select Summary Phase > Insert New Phase.
3. Enter a phase name when prompted (or accept default name).
4. The Phase Adjustment tool-bar will appear. Select Phase start and/or phase end and use the move buttons (right or left arrows) to adjust the phase start and end times. You can zoom to the starting or ending area of interest for precise control.
5. Phase Start and Stop time may also be adjusted by dragging and dropping the Phase Start or Stop line markers.
6. Close the Phase Adjustment tool-bar when finished (click on small red close icon).

Additional Graph Options:

- The phase labels (vertical lines, horizontal arrow, phase name)on the graph may be optionally hidden.
- The phase name may optionally be displayed near the bottom or near the top of the graph.
- The Phase Adjustment tool-bar can be opened using the Adjust Phase menu item. Take care to select the appropriate phase start or end when multiple phases have been defined.

Once a phase has been defined, the **summary data** view statistics and the graph will be for the phase data only when the **Zoom to Phase** item (in the graph options menu summary phase items) is used.

Notes:

- *The summary page may be printed or previewed using the Current View print icons located in the upper left corner.*

- *The summary page for a phase may be included in a report (Report Setup > Item Selection > Phase Handling).*

- *Sub-summaries can also be generated by using the Graph options menu to create a study from a zoomed in data range, and then subsequently accessing that new study discretely.*

8.4.8 Excluding Data:

During the course of a test, validation or process study there may be excess data logged. This is especially true with radio data, as all received data is logged regardless of its importance. Several methods exist to remove or control extraneous or non-important data; and there are three general types of data control methods:

- **Data Exclusion**: excluded data is still accessible (is not deleted), it is simply not viewed or printed for the current report.
- **Data Deletion**: data can be deleted (administrator permission levels only) using the Database Utilities tool (expand Configuration Tools) or reports view graph or data grid.
- **Data Restriction**: data flow can be restricted such that it is logged into the database but marked as undesired; marked data can be viewed or printed if specifically requested. Data can be marked as undesired (administrator or power permission levels only) using the reports view graph or data grid. Incoming RF data can be marked as undesired by disabling RF in system tools, device configuration for any logger channel.

The user should consider the appropriateness of omission, deletion or restriction relative to the process, test or validation and possible regulatory requirements.

Data Exclusion Techniques

Data omission techniques apply to the exclusion of data from reports. These are implemented from within the Data View window (see Chapter 8: Creating Reports).

- **Use the Graph**: data can be excluded by zooming in on a desired range and either excluding the visible data or excluding all non-visible data. The data interval for a zoomed range may also be reduced by excluding those rows of data that do not conform to a selected interval.
- **Use the Data Grid**: selected data rows or columns (logger channels) may be excluded.
- **Compress the Data**: When printing data, the user may specify the data print interval for a report, or for a phase within the report data set.
- **Create a Study**: use the graph to zoom in on a range and create a study for that range. Access that study (thereby "excluding" data from the original data set).
- **Create a Study from Radio Data**: use the Real Time data view window to define a study name and manually start and stop it.

Notes:

- *Data omissions are recorded in the report audit trail; this activity log should be included in reports intended to comply with 21 CFR Part 11 or similar regulations (Report Setup > Item Selection > Security Summary). Study creation is a system audited event and may require a digital signature.*

Data Deletion or Marking data as Undesired

When a higher security mode is enabled, Data Deletion is restricted to the Admin permission levels. Both Admin and Power users may mark data as undesired.

- Data Deletion permanently removes data from the database.
- The Mark as undesired option tags the data so that it will no longer be normally available, but may still be viewed if the "**Include data marked as undesired**" option is used when first accessing or selecting data.
- Data deletion from the reports graph or grid may be completely prohibited in the system setup, in which case the menu item will not be available. See Section 2.2.1: Data Limits, Exceptions and Deletion Options for details.

Deletion or marking data can be performed by:

- **Access Configuration Tools > Database Utilities**: data may be selected in various ways and deleted outright or archived (removed from the active database but still available for viewing at some subsequent date).
- **Use the Data View Graph:** A zoomed in range may be deleted or marked as undesired.
- **Use the Data Grid menu**: delete or mark data the data by selecting rows, columns or individual cells.
  All data deletion or marking events are logged in the audit trail. When used, an option is provided to enter a comment or explanation for the action.

Data Restriction Techniques

- **Read only the desired data**: use the data preview button and select a time range to read. This feature is only available if enabled in the System Setup.
- **Start and stop radio data reception manually:** Use the Wireless Data start or pause buttons. Manual control must be configured in the System Setup.
- **Enable or disable individual loggers**: Using the browser view options menu from within Configuration Tools, the logging of radio data into the database may be enabled or disabled. Access to Configuration Tools is restricted to Admin and Power permission levels. Received data is still saved, but is marked as undesired.
- **Data destination control**: DT Pro allows the user to specify the physical location of the database. This location may be on the local computer, on a server, and it is possible for multiple locations to exist. Data is saved in only one location; the user (with Admin or Power permission

level) may change where the data saved so as to better organize the database (e.g. production and quality control departments could maintain separate databases for routine activities, but also have a common one for shared data). This method requires the DT Pro LAN Server edition, see Section 11.2: Database Configuration Utilities for details.

Notes:

- *These methods are audited events and may require a digital signature.*

8.4.9 Managing Studies:

Links are provided to specific details on items that may be if interest. The reader may alternatively review all of the general information given on this page and then follow the tutorial links (bottom of page) for a comprehensive review of the DataTrace Pro reporting system.

About Studies

- A study is the data logged by a defined by a group of data loggers (and their individual channels) over a defined time range. Time range is defined by a starting time and an ending time.
- A study may have a user defined name, or use the start time as a default name.
- A study allows relatively instant access to data in a controlled fashion, typically by accessing the Recent Studies browser view folders.
- Associated with studies is a programming report, indicating the members (loggers) of the study, as well as when and how they were programmed.

Note: there is no restriction on study names. Duplicating study names is allowed, but should be avoided within the "Recent Studies" time frame (30 days or 6 studies).

Studies can be created in several ways as detailed below.

8.4.9.1 Creating Studies

Programming and Reading

A study is created each time a group of loggers is programmed. A study name may be defined in the text box located at the top of the programming window. Initially, the study does not have a data end time, therefore, it is not associated with data and does not appear in recent studies. When loggers are read, an end time is assigned for each logger in the study; depending on the read options used, the end time may be the same or different for each logger. While reading a group of loggers with a defined study, the browser view will indicate which members have been read and which are yet to be downloaded.

From the Graph Subsets

A study can be created from a subset of data while viewing the graph in the Data View window (Chapter 8: Creating Reports). Zoom in on the desired data range; select Create Study from the graph options menu. The new study may also be created after the exclusion of undesired data rows or loggers.

Study creation is an audited event which may require a digital signature.

8.4.9.2 Manual Study Control from the Real Time Radio Data View

A study can be started and stopped or created during the reception of real time radio data. Use the study icons at the top of the Real Time view to set or edit a study name, start the study and stop the study. This process does not affect data acquisition; data logging by devices will continue and received radio data is still saved; it is only setting the data start time and end time for the members for the study.

- Manually controlling studies is available only if enabled in the System Setup.
- Manual study control is available only for named studies (the user defined a study name when programming the loggers).
- When viewing radio data, manually controlling studies is available only if the real time view was accessed using the Sort By Study option and a study was selected (right click on Wireless Data browser view to expose sort options menu).
- When a study is selected, all members will be displayed in the real time view (including any non-RF capable loggers).
- When the start or stop time of a study is set, the settings are applied to all members of the study (including any non-RF capable loggers).
- Once a study has been started, a new study may not be defined until the original has been stopped.
- If a new study is defined, its members will be all of the loggers in the current view.
  See the Section 6.4.5 Study Manual Control topic for further details.

8.4.10 Data Control Methods

During the course of a test, validation or process study there may be excess data logged. This is especially true with radio data, as all received data is logged regardless of its importance. Several methods exist to remove or control extraneous or non-important data; and there are three general types of data control methods:

- **Data Exclusion**: excluded data is still accessible (is not deleted), it is simply not viewed or printed for the current report.
- **Data Deletion**: data can be deleted (administrator permission levels only) using the Database Utilities tool (expand Configuration Tools) or reports view graph or data grid.
- **Data Restriction**: data flow can be restricted such that it is logged into the database but marked as undesired; marked data can be viewed or printed if specifically requested. Data can be marked as undesired (administrator or power permission levels only) using the reports view graph or data grid. Incoming RF data can be marked as undesired by disabling RF in system tools, device configuration for any logger channel.

The user should consider the appropriateness of omission, deletion or restriction relative to the process, test or validation and possible regulatory requirements.

Data Exclusion Techniques

Data omission techniques apply to the exclusion of data from reports. These are implemented from within the Data View window (see Chapter 8: Creating Reports).

- **Use the Graph**: data can be excluded by zooming in on a desired range and either excluding the visible data or excluding all non-visible data. The data interval for a zoomed range may also be reduced by excluding those rows of data that do not conform to a selected interval.
- **Use the Data Grid**: selected data rows or columns (logger channels) may be excluded.
- **Compress the Data**: When printing data, the user may specify the data print interval for a report, or for a phase within the report data set.
- **Create a Study**: use the graph to zoom in on a range and create a study for that range. Access that study (thereby "excluding" data from the original data set).
- **Create a Study from Radio Data**: use the Real Time data view window to define a study name and manually start and stop it.

Data omissions are recorded in the report audit trail; this activity log should be included in reports intended to comply with 21 CFR Part 11 or similar regulations (Report Setup > Item Selection > Security Summary). Study creation is a system audited event and may require a digital signature.

Data Deletion or Marking data as Undesired

When a higher security mode is enabled, Data Deletion is restricted to the Admin permission levels. Both Admin and Power users may mark data as undesired.

- Data Deletion permanently removes data from the database.
- The Mark as undesired option tags the data so that it will no longer be normally available, but may still be viewed if the "**Include data marked as undesired**" option is used when first accessing or selecting data.
- Data deletion from the reports graph or grid may be completely prohibited in the system setup, in which case the menu item will not be available. See Section 2.2.1: Data Limits, Exceptions and Deletion Options for details.

Deletion or marking data can be performed by:

- **Access Configuration Tools > Database Utilities**: data may be selected in various ways and deleted outright or archived (removed from the active database but still available for viewing at some subsequent date).
- **Use the Data View Graph:** A zoomed in range may be deleted or marked as undesired.
- **Use the Data Grid menu**: delete or mark data the data by selecting rows, columns or individual cells.

All data deletion or marking events are logged in the audit trail. When used, an option is provided to enter a comment or explanation for the action.

Data Restriction Techniques

- **Read only the desired data**: use the data preview button and select a time range to read. This feature is only available if enabled in the System Setup.
- **Start and stop radio data reception manually:** Use the Wireless Data start or pause buttons. Manual control must be configured in the System Setup.
- **Enable or disable individual loggers**: Using the browser view options menu from within Configuration Tools, the logging of radio data into the database may be enabled or disabled. Access to Configuration Tools is restricted to Admin and Power permission levels. Received data is still saved, but is marked as undesired.
- **Data destination control**: DT Pro allows the user to specify the physical location of the database. This location may be on the local computer, on a server, and it is possible for multiple locations to exist. Data is saved in only one location; the user (with Admin or Power permission level) may change where the data saved so as to better organize the database (e.g. production and quality control departments could maintain separate databases for routine activities, but also have a common one for shared data). This method requires the DT Pro LAN Server edition, see Section 11.2: Database Configuration Utilities for details.

These methods are audited events and may require a digital signature.

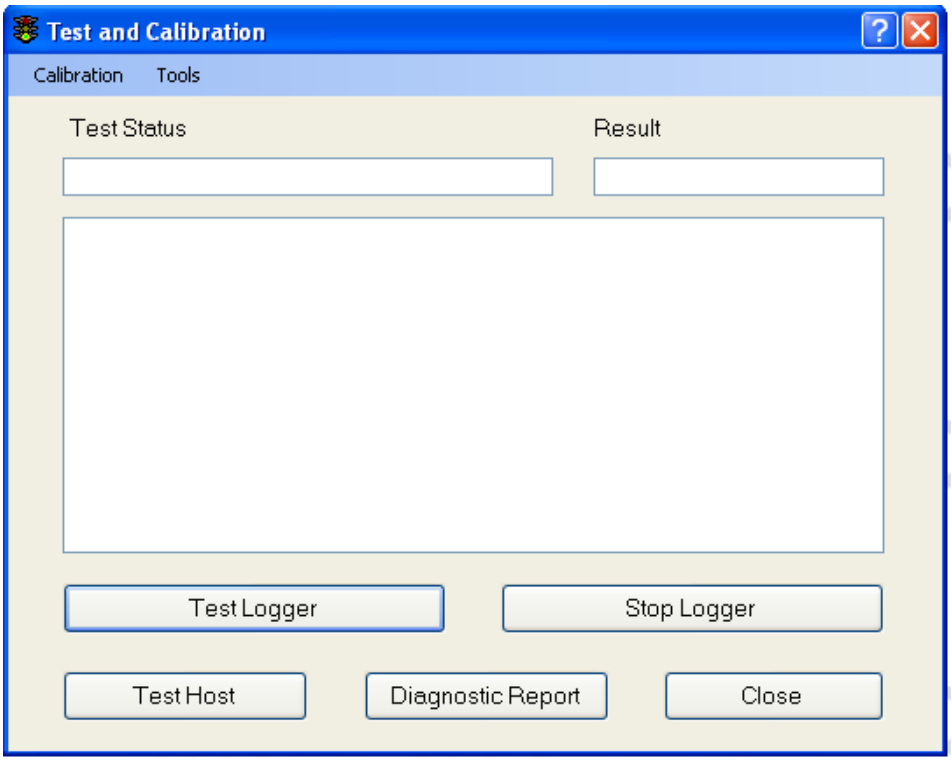
Chapter 9: Testing Loggers

Normally, before you start to program your loggers to go into a process, it is highly recommended that a test is done on them, to ensure that they function properly. In this chapter, you will learn how to use the Test Logger function in DT Pro.

To launch the Test and Calibration window, do the following:

- Expand **Logger Functions** and select **Test and Calibration** to access the Test and Calibration window.
- *If your system has been configured for Environmental Monitors Only, Logger Functions will not be visible.*

Notice: The following test functions only exercise communications and data logging. They do **not** test radio communications.



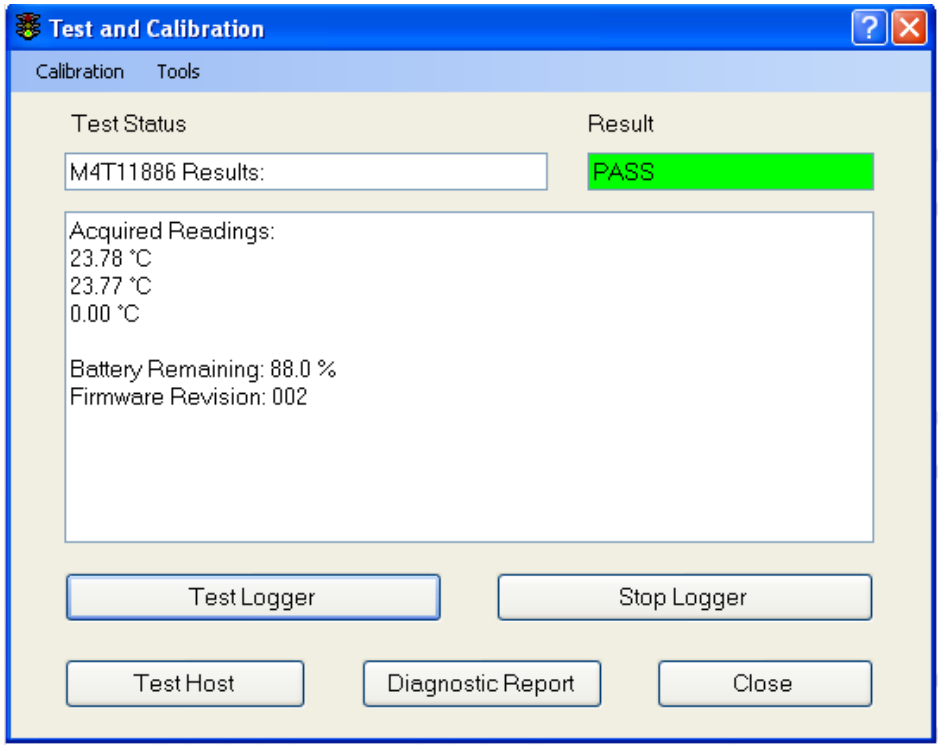
9.1 Test Logger

1. Place the logger in the interface.
2. Click the "Test Logger" button.

Test results will be displayed within about 12 to 15 seconds (or less). If 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.

Logger test results and battery changes are recorded in the system's audit trail.

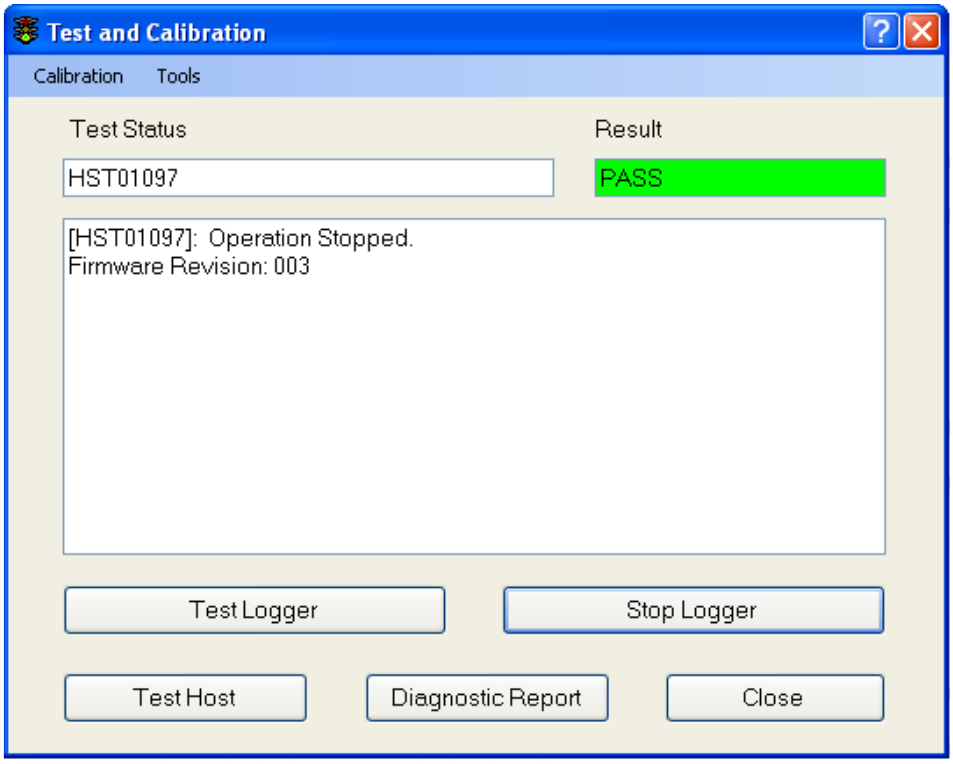
DT Pro v1.2 is compatible only with MPRF firmware version "001" or newer. When a logger is tested, if the current firmware version is too old, the need to upgrade will also be displayed. The firmware upgrade utility is accessed from the Tools menu (see below).



9.2 Test Host

Applies to radio capable Host interfaces only. Click the "Test Host" button to verify proper USB communications. Test result and firmware revision level will be displayed.

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

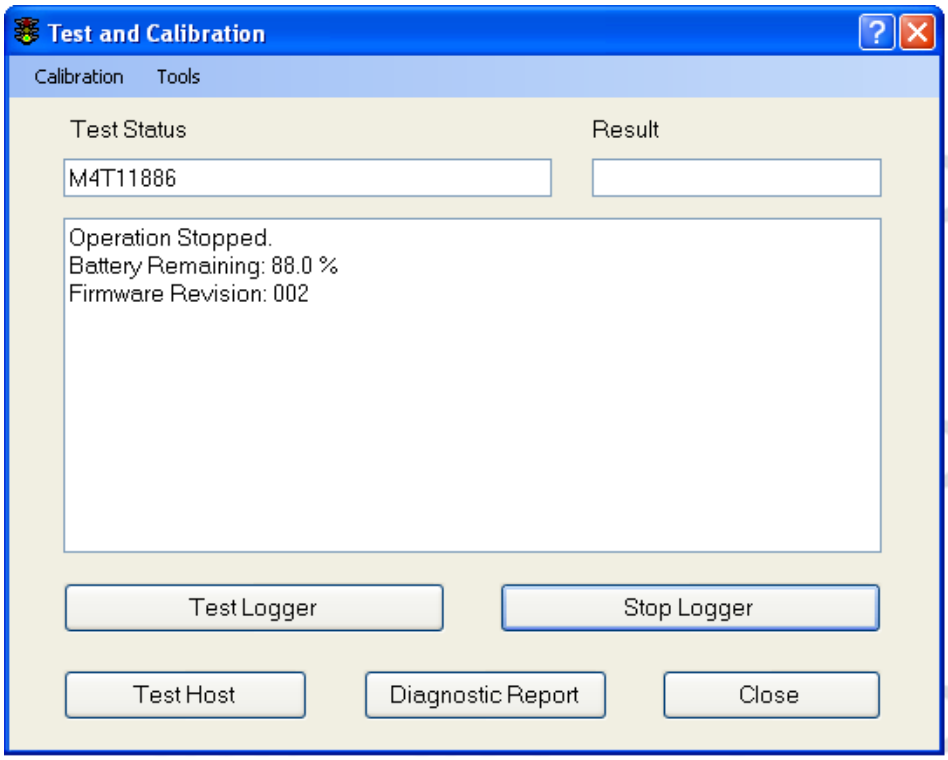


9.3 Stop Logger

This "test" stops data logging and radio transmission. Data may be downloaded at a later time. Firmware revision and battery status will be displayed.

This is normally used for radio loggers after all the desired data has already been received via RF. It is also used to stop programmable repeaters.

Notice: When testing or stopping loggers after the battery has been changed or the logger has reset, a message will inquire if a new battery was installed will be generated. See Battery Replacement Procedure in the DT Pro Help File for details.



9.4 Diagnostic Report

This "test" reads a logger and saves the results in a text file. The file also contains various logger configuration parameters. This report may be useful to factory service personnel when providing assistance or diagnosing logger problems.

9.5 Calibration menu

- **Standard Calibration**: provides access to a 1 or 2 point calibration check or adjustment utility (same method as DTW or DTRF software).
- **Automated Verification**: provides access to a multiple point user defined profile calibration check or adjustment utility. This utility can interface with various reference and control equipment and perform completely automated calibration verification. *See also: Chapter 10: Calibrating Loggers*

9.6 Tools menu

- **New Battery**: After changing a battery, MPIII and MPRF Loggers require a battery reset procedure. This button will perform that procedure directly. The Test Logger button will also identify the potential need for the procedure during the course of a standard test and inquire whether to perform it. *See*

also: Battery Replacement Procedure in the DT Pro Help File for more information on how to change batteries in loggers.

- **Upgrade Firmware**: This utility allows the firmware of an MPRF logger to be upgraded. *See Section 9.8: Firmware Upgrade for details.*

- **Set Host Channel**: The channel of the host receiver may be manually set using this item. **Warning**: changing the host channel can result in data loss from devices transmitting on the original channel. This item is enabled only after a successful Test Host.

9.7 Standard and Low Temperature Battery Management

Warning: Do not expose low temperature batteries to temperatures greater than 85° C (185° F). Failure to observe temperature limits may result in erroneous data, a ruptured battery, a damaged logger and/or personal exposure to toxic chemicals with associated health hazards.

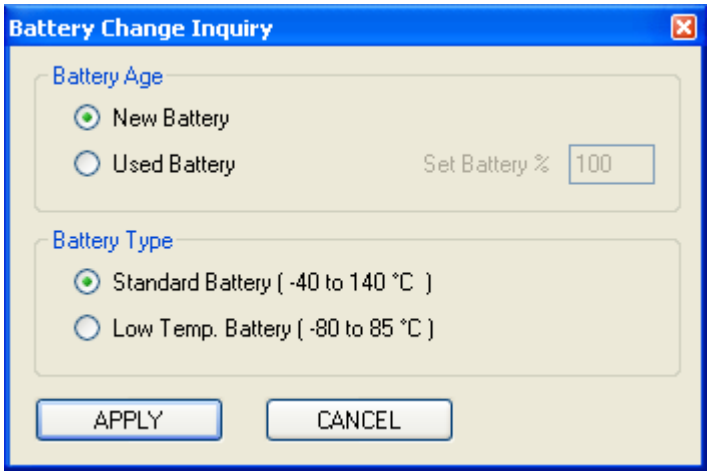
Notice: Always dispose of lithium batteries in accordance with your local regulations.

The described features are applicable only to MPRF loggers with firmware revision "002" or newer.

9.7.1 Battery Management Utility

It has been observed that the use of standard MPRF batteries for extended periods at temperatures less than -40° can result in erroneous data or premature cessation of data acquisition. To address these issues, Mesa Laboratories, Inc. has identified a battery with improved low temperature performance. This Low temperature battery is specified for use only up to +85° C (185° F) The battery management utility provides tools to manage the low temperature battery.

From within the Test and Calibration window, the utility is accessed from the "Advanced" button available during the standard "Has a new battery been installed" inquiry. The inquiry is generated after the detection of a battery change when a "Test Logger" or "Stop Logger" is performed. Alternatively, the inquiry may be generated from the Tools menu, "New Battery" item. See screenshot below:



The utility has options to identify the battery type (Standard or Low temperature). When the Low type is chosen, any subsequent testing or programming of the logger will indicate that the logger has the Low type (so as to avoid exposing the logger to higher temperatures).

The utility also has options for identifying the battery as a new or a used battery. The logger battery gauge is only an estimate based on the installation date of the battery and usage of the logger. When the

used battery option is selected, the battery gauge may be set to any desired value (0 to 100%), and will decrement from that point as the logger is used.

Once the settings have been established, click the "Apply" button to transfer the information into the logger.

Notice: Loggers with Low type batteries will not log data greater than 90°C (194°F).

9.7.2 Procedure for reusing batteries

If it is desired to remove a battery from a logger with the intention of reusing it at a latter time (e.g. replacing a Standard battery with the Low type or vice versa, removing a battery for long term storage), prior to removing the battery, in the Test and Calibration window, Test or Stop the logger and record the current battery gauge reading. This record establishes what the used battery gauge setting will be when the battery is used again. Remove the battery and store it along with the recorded value (it is acceptable to record the value directly on the battery using an indelible ink pen). When it comes time to reuse the battery, install it in the logger and access the battery management utility; set the battery type, select the Used Battery option, enter the previously recorded battery gauge value for the battery and click "Apply".

9.7.3 Visually identifying battery type

The Standard temperature battery is typically mostly white in color, with a black top (+), and is labeled with the absolute maximum exposure of 150°C (302°F); Xeno part number XL-060H

The Low temperature battery is typically mostly gray and light green in color, with a blue top (+), and is labeled with the absolute maximum exposure of 100°C (212°F); Xeno part number XL-060F.

9.8 Firmware Upgrade

The firmware used by MPRF loggers can be upgraded if necessary. MPIII loggers do not support field firmware upgrade.

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 may be available for download from the Mesa Labs web site (www.mesalabs.com); alternatively, please contact your DataTrace representative for assistance in obtaining the most recent firmware file.

DT Pro requires MPRF loggers and RF interfaces to have firmware version "001" or newer. If Repeaters, routers or Environmental Monitors are to be used, DT Pro requires all RF capable device (including loggers) have firmware version "001" or newer.

Upgrading firmware does not affect logger calibration.

9.8.1 Logger Upgrade Procedure:

1. Start DT Pro
2. Put the logger in the interface, access the Logger Test window and Click the Stop Logger button.
3. Verify proper communications occurred and the serial number of the logger is indicated.
4. Access the Tools menu and click on the Upgrade Firmware Item.
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 were it was previously saved (e.g. after a download), or in the DT Pro Upgrade folder (typically C:\Program Files\DataTrace Pro\Upgrades).

6. Wait for DT Pro to load the new firmware into the logger.
7. When finished, it is advisable to Test the logger and confirm the new revision.

9.8.2 Host Interface Upgrade Procedure:

Notice: Non-RF (MPIII type) interfaces do not have firmware nor require firmware upgrades.

1. Start DT Pro
2. Access the Logger Test window and Click the Test Host button.
3. Verify proper communications occurred and the serial number of the host interface is indicated.
4. Access the Tools menu and click on the Upgrade Firmware Item.
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 were it was previously saved (e.g. after a download), or in the DT Pro Upgrade folder (typically C:\Program Files\DataTrace Pro\Upgrades).
6. Wait for DT Pro to load the new firmware into the interface.
7. When finished, it is advisable to "Test Host" and confirm the new revision.

Problem Resolution:

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 logger again to verify the actual firmware version, and if needed, try upgrading again prior to returning the logger for service or upgrade at the factory.

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

Chapter 10: Calibrating Loggers

Calibration is the act of quantifying the accuracy of a measurement relative to a known standard. DT Pro provides two utilities for calibration. The user may optionally only check (verify) the accuracy of a logger or environmental monitor; or, may also adjusting the device so that it more closely (or perfectly) agrees with the reference standard.

10.1 Restore Factory Defaults

This utility is provided to recover from a bad calibration. When used, the Logger will be returned to the calibration coefficients of the last factory service. If the logger has two channels (e.g. temperature and humidity), both channels will be restored.

Note: this utility does not affect nor restore Cryogenic (-80°C) calibration correction factors.

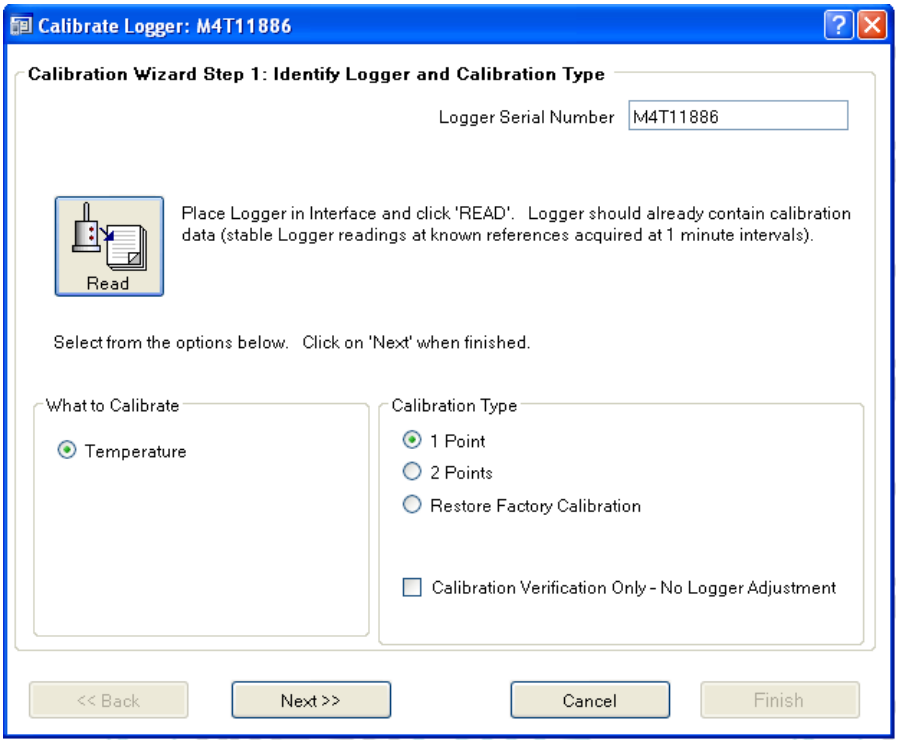
10.2 Standard Calibration Utility

If your system has been configured for Environmental Monitors Only, 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 (same method as DTW or DTRF software), reference data is obtained through external means and manually entered by the user. This utility is not compatible with environmental monitors. Logger adjustment is made via an offset correction (1 point mode) or a slope and offset correction (2 point mode).

This utility can calibrate Logger models which support field calibration, which are MPIII Temperature, MPIII RH, MPRF Temperature and MPRF RH.

This utility also includes a Cryogenic (-80° C) calibration option for MPRF loggers that possess this measurement range.



Here is the procedure to perform a standard calibration process:

1. In order to calibrate Loggers, the Loggers must be programmed and allowed to acquire data at 1 minute intervals. Expose the Logger to a known reference environment. Allow sufficient time for stable readings to be recorded and note the time of stability.
2. The utility allows either 1 or 2 point calibrations. If a 2 point calibration is to be performed, once the Logger has been allowed to record the stable first reference point, expose the Logger to the 2nd point and allow the Logger to stabilize and record the 2nd point.
3. After stable logger and reference data has been acquired, access the Standard Calibration Utility: expand **Logger Functions**, and open the **Test** window. From the top menu of the Test window, select **Calibration > Standard.**
4. **Wizard Step 1:** Place the logger in the interface, choose the logger type and click the "Read" button.
5. **Wizard Step 1:** Select what to calibrate (temperature or RH).
6. **Wizard Step 1:** Select the calibration type (one or two point calibration, cryogenic (-80° C) or Restore factory defaults).
7. **Wizard Step 1:** Select whether the calibration is only a verification (logger will not be adjusted). Click Next**.**
8. **Wizard Step 1:** If Restore Factory Defaults is selected, simply click Finish. The Logger will be returned to the calibration coefficients of the last factory service**.**
9. **Wizard Step 2:** Based on the known reference environment and what time the calibration environment became stable, select a data point for the Logger, and enter what it should have been (the reference value). Do so for both points if a 2 point method was selected.
10. **Wizard Step 2:** Document the test name or Lot number if desired, and click Next.
11. **Wizard Step 2:** Review the results.
12. **Wizard Step 3:** Enter Comment and Name for documentation purposes, if desired. Click Finish.

If the calibration was not a verification only (Item # 7), the logger will be adjusted (new calibration coefficients will be loaded).

The calibration data will be saved and a calibration report will be available (expand **Reports**, select **Calibration**).

Notice: The cryogenic (-80° C) calibration option is available only for MPRF loggers that have had the cryogenic calibration option installed at the factory, and only when temperature data < -50°C exists within the logger. 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 logger is accurate at -40° C. The Restore Factory defaults option does not affect the cryogenic correction factor, nor restore it if it has been changed from the factory original value.

Notice: When performing 2 point calibrations, the 2 reference values should be different by at least 20, and the logger value may not be more than 20 different from the corresponding reference value.

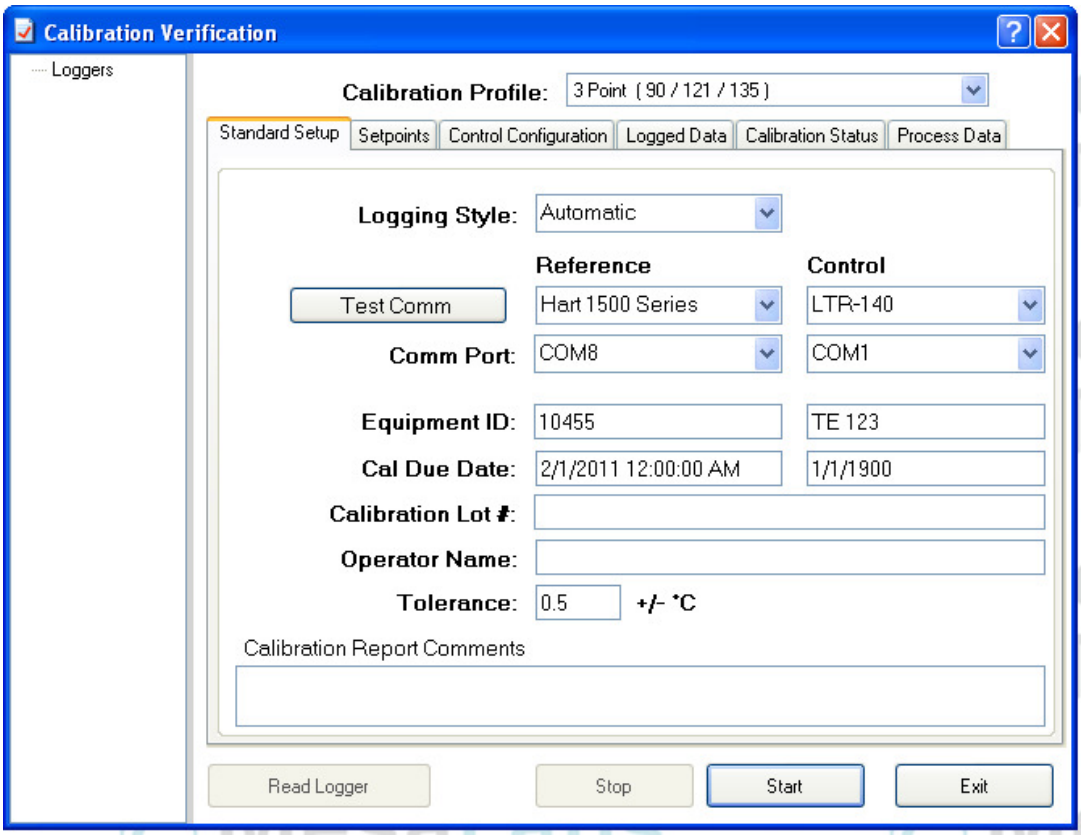
10.3 Automated Verification Utility

The automated verification utility is a multiple point user defined profile calibration check or adjustment utility. This utility can interface with various reference and control equipment, receive and process RF data, and perform completely automated calibration verification. Reference data may be automatically acquired or manually entered. Optional logger or monitor adjustment is made via a best average offset correction (one set-point) or a best fit (linear least squares regression) slope and offset correction (two or more distinct set-points).

This type of automated verification is commonly performed prior to or after (or both) a process validation. The resulting calibration reports may be printed separately or incorporated into process validation or other reports.

This utility allows logger accuracy to be evaluated relative to reference standards utilizing user defined set-points, control and evaluation criteria. A calibration report may be generated from the results of an evaluation. If desired, a logger can also be adjusted (calibrated) to more closely match the reference.

The normal way to use this utility requires the computer be connected to a reference device, e.g. a thermometer, via a serial COM port. When the verification is running, the utility will read the reference value from the device. If desired, the computer may also be connected to an environment control device, e.g. a temperature bath, and the utility can transmit the desired set-points to this device. Some devices can perform both reference and control functions, and the automated verification utility can be configured for this.



10.3.1 Access and Logger selection

The verification utility window is accessed from the options menu of the browser views (except reports view). The process also defines the loggers that are to be verified. The methods for access and selection are:

- Program a group of loggers to be verified. From the Logger Functions browser view, select the Programmed group, right-click for the options menu, and select Cal Verification.
- If wireless data is active, select a group or an individual logger in the browser view, right click for the options menu, and select Cal Verification.
- From the Configuration Tools browser view, select a group or an individual logger, right click for the options menu, and select Cal Verification. *Requires Admin or Power permission level.*
- Once the verification window is open, the loggers to be verified are displayed on the left side; a logger can be removed by selecting it, right clicking for an options menu, and selecting "Remove Device".
- If Cal Verification is accessed for an individual logger, and the verification window is already open, the logger will be added to the existing verification group.

Notes:

- *It is best, but not absolutely required, to declare all of the loggers to be verified prior to commencing a verification process.*
- *If real time logger stability evaluation is desired (for RF capable loggers), they must be included in the group and radio communications must be active.*

Once the automated verification utility window is open, commencing verification involves selecting from a pre-defined **Calibration Profiles** box, and clicking the **Start** button. In the window, there are six tabs which are used to define how the verification is performed, display results or perform logger adjustments. The functions of each tab are:

10.3.2 Standard Setup

This tab is used to define what equipment (if any) is connected to the computer, how it will be used and identified in calibration reports, and set a verification tolerance.

- **Logging Style**: Automatic or Manual. If Automatic, the utility will issue set points to the control device, evaluate stability and log data per set point and control settings. If manual, the user will decide when the reference data will be logged by manually clicking the Log Data button (in the status tab).
- **Reference**: Select the device which will provide the reference value. If manual is selected (not compatible with Automatic logging style), the user will manually input a reference value when manually logging data. If wireless logger is selected, the reference logger must be specified using the browser view options menu.
- **Control**: Select the device which will control the environment the logger is exposed to (if different then the Reference device). This selection will not be available if the Logging Style is manual or the reference device itself also provides control.
- **Comm Port**: Define on which serial port of the computer the reference and control device is connected.
- **Equipment ID, Cal Due Date**: Enter how you want the reference or control devices to be identified on the calibration report and when their calibration is due.
- **Calibration Lot #, Operator Name**: Additional information for the calibration report.
- **Tolerance**: Set the pass / fail tolerance for the verification.
- **Comments**: Additional information for the calibration report (optional).

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.*

10.3.3 Set points

The grid in this tab is used to define the set points for the verification process, in what order they will occur, and define a minimum soak time. *These items are not applicable in manual control mode.*

- Use the Add and Delete buttons to create or remove rows.
- Use the up or down arrows to alter the relative position of rows.
- In each row, enter the desired set point
- For each set point, also set a minimum dwell time (soak).

Notes:
- *The order of verification will be from the first (top) row to the last.*
- *There is no inherent limit on the number of set points; if it is desired to log several calibration points at each set point, use "Point To Log" option in Control Configuration rather than duplicating set points.*
- *In the simplest control scheme (no stability evaluation), a set point is issued, and after soak time has elapsed, a calibration data point is logged.*

- *In more complex control schemes (e.g. with stability evaluation), evaluation does not begin until after soak time has elapsed; a minimum soak time should still be defined.*

10.3.4 Control Configuration

This 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. Calibration profiles may be created, named or removed (Create New and Delete buttons); if a new profile is created, it will be a copy of the previously selected profile.

Control Parameters

The items on the left determine the control style:

Soak Only: Data for each set point will be logged after soak time has elapsed
Reference Stability: After soak time has elapsed, the reference data must also meet stability criteria (items on right side) before data is logged.
Reference and Logger Stability: After soak time has elapsed, the reference data and data from wireless loggers must also meet stability criteria (items on right side) before data is logged.
Warn if stability is not achieved: Not applicable to "Soak Only"; if set, and stability is not achieved within the **Warning Limit** setting time, a warning is issued (pop-up message, sound or e-mail using the completion settings).

Stability Evaluation Parameters:

- **Reference Stability Limit**: The acceptable minimum to maximum range of reference values during a dwell limit period.
- **Logger Stability Limit**: Same as above for logger values.
- **Dwell Limit**: The length of time incoming data is evaluated in order to determine stability.
- **Set point Deviation Tolerance**: How close the reference value must be to the set point.
- **Warning Limit**: see above.

Notes:

- *If stability evaluation is used, the dwell limit should be at least three or four times larger than the logging interval (see below).*

Logging Parameters

- **Points To Log**: How many data points will be logged for each set point. If more than 1, a calibration report will also include the spread (stability) at each set point for the evaluated loggers.
- **Logging Interval**: How often the reference device is polled. This setting should also match the logging interval used by or programmed for the loggers being evaluated.
- **Warn if Deviation is out of Tolerance**: If during the course of the verification wireless logger data is found to be out of tolerance at one particular set point (after stability criteria has been met), a warning message is generated and the process will pause until the message is acknowledged (allowing the user to take corrective action; loss of RF communications will also cause this warning to be issued).
- **Completion Options**: The items on the left set various self-explanatory options for what happens when the process is complete (Sound warning, Send E-mail, Reset to First Set point).

10.3.5 Logged Data

- The top grid in this tab show the stable reference data that has been logged.
- The bottom grid shows data for wireless loggers being evaluated, and the result of tolerance evaluation for each reference point.
- The bottom grid will also show the results for non-wireless loggers (MPIII) after they have been read using the **Read Logger** button in the Process Data tab.

10.3.6 Calibration Status

Once a verification is started, this tab shows the process status: The current set point, reference device, wireless 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 mode is selected, a "Log Data" button will be visible. This button will be enabled only if reference stability criteria have been met.

Note: General calibration status such as "In Progress" or "Finished" is displayed on window title bar.

10.3.7 Checking /Verifying Non-Radio Loggers

Note: The data from wireless RF loggers is evaluated as it is received and can be seen in the logged data tab.

- Access the **Process Data** tab. Place the logger in the interface.
- Use the Read Logger button to identify and download data from non-wireless (MPIII) loggers, or loggers with the radio functions disabled or with intermittent radio communications. The act of reading a logger will (after confirmation) 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).
- Once the Logger has been read, its data will be automatically evaluated. The As Found box will indicate Pass or Fail relative to the specified Tolerance.
- Logger results (e.g. minimum and maximum errors) can also be seen in the Logged data tab.

10.3.8 Adjusting / Calibrating Loggers

Access the **Process Data** tab. This tab provides tools to calculate and load adjustment parameters into loggers.

- Use the Read Logger button to identify and download data from non-wireless (MPIII) loggers, or loggers with the radio functions disabled, or intermittent RF communications.
- If it is desired to adjust a logger or monitor, select the **calibration style**: DT Pro uses a best fit linear regression to calculate the best adjustment. If only one set point was used, use the Offset only option. If more set points were used, and these span the intended range of measurement, use the Sloe and Offset calibration option.
- The statistical (predicted) results of the adjustment calculation are shown in the grid and the boxes on the left.
- Use the Apply Calibration to load the adjustment result into a loggers.
- If selecting from wireless loggers (drop down box) and using the Adjust Via RF option, RF communications must be active and it may take several intervals before the adjustment occurs.
- If adjusting via PC Interface, place the logger in the interface and read it (regardless of any known data or results) in order to identify the logger to the system; the, Apply Calibration.

10.3.9 Calibration Reports

The calibration reports for the entire group may be accessed using the Cal Report button (top left). Calibration reports can also be accessed by expanding the Reports view of the main window, and selecting Calibration.

Calibration reports can also be included as part of a process, test or study report; either as a Pre-process or Post-process verification (depends of date and time of the verification relative to the process or test data). *See Section 8.4.3 Report Items.*

10.3.10 Metrological Considerations

- DT Pro does not evaluate the quality or precision of neither references nor suitability for use of either reference or control equipment. A typical use for the Comments field is to document or describe the calibration system uncertainty or specifications of the equipment used.
- It is highly recommended that after any adjustment, a second verification be performed (such that the certified "As Left" value is not a prediction but an actual observation equal to the "As Found" value).
- There are only minimal limits on how much a device can be adjusted; once an adjustment has been made, any previous certifications are no longer valid.
- If a slope and offset adjustment is made, the calibrated range of the logger should be considered to be from the minimum set point to the maximum set point.
- Calibration drift is not necessarily linear, to effectively characterize most DataTrace loggers across their entire specified operating range, at least four to six set points are required.
- All temperature sensors are subject to error due to immersion depth. It is preferable to calibrate DataTrace temperature loggers in a bath with the 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 logger is also near the temperature it will be during process measurements.

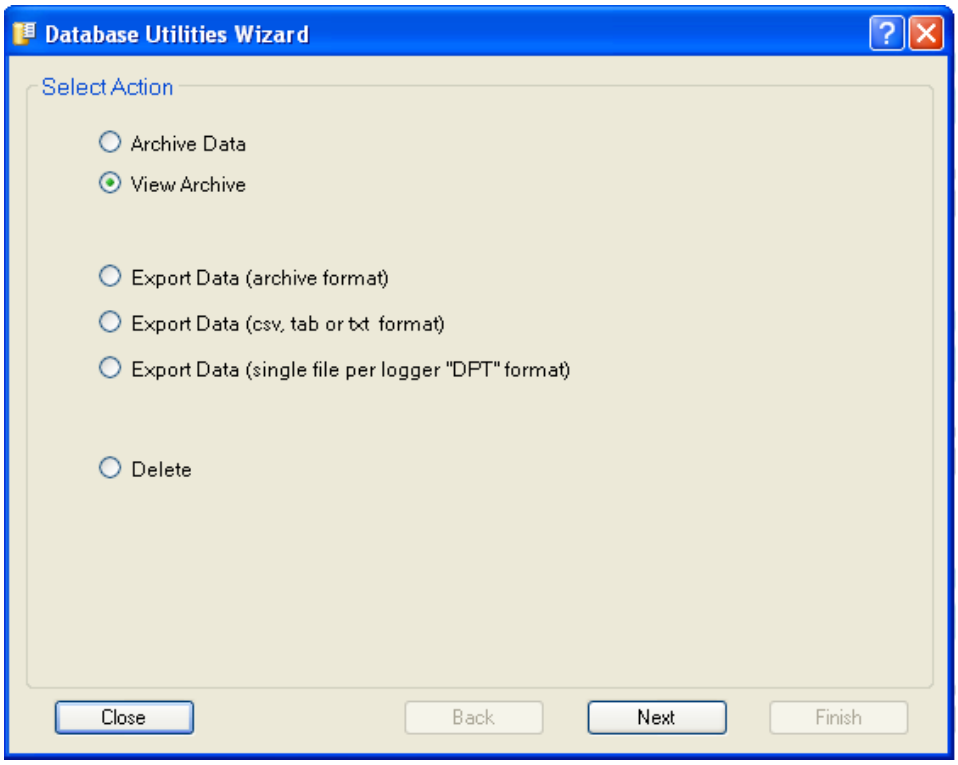
Mesa Labs will entertain requests for the addition of communication capabilities with new reference or control equipment.

Chapter 11: Database Management

In this chapter, you will learn different functions within the Database Management module. This includes the following topics:

- Archive Data: This is a function of the Database Utilities Wizard, allowing users to archive old data
- View Archive Data: This is a function of the Database Utilities Wizard, allowing users to view archives
- Export Data: This is a function of the Database Utilities Wizard, allowing users to export data to other formats such as CSV, or TAB.
- Database Backup: This is the function of the Database Configuration Utilities, allowing admin users to backup the entire DT Pro database
- Database Configuration: This is the function of the Database Configuration Utilities, allowing admin users to change the database connection configuration to connect to a remote DT Pro database.

11.1 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:

- **Archive Data**: Creates a binary and secured archive data file; after the file has been created, data is deleted from the database.
- **Export Archive**: Creates a binary and secure archive data file; the data is NOT deleted from the database.
- **View Archive**: Opens an archive file for viewing or report printing using the standard data view window.
- **Export Data**: Creates a file of the data suitable for importing into other applications or e-mailing. Supported export formats are: comma separated value (*.csv), tab separated (*.tab), text file (*.txt) and DPT (old DTW style single logger format included for backward compatibility).
- **Delete Data**: This option is available only to the DT Pro system administrators.

Notes:

- *The Data Management tool is not available while radio data reception is active. In a LAN environment, Archiving and Report Template exporting are restricted to the host computer (the physical location of the database) only.*
- *When security is enabled, accessing the Database Utilities Wizard will require a user account with "Administrator" access permissions.*
- *Access to these utilities is not available while RF data reception is active.*

The performance of the DT Pro database (e.g. the time it takes to retrieve data or run a report) is dependant on the amount of data in the database. Older data can be archived and viewed if needed, and in doing so performance can be enhanced.

A DT Pro archive file contains not only measured data, but also a copy of the system configuration, alarm histories, study definitions, audit trail entries and other information at the time the file was created. An archive therefore preserves configuration information such as Logger Tag names or alarm set points, information which might subsequently change.

For these two reasons it is highly recommended the database be periodically archived.

11.1.1 Creating an Archive

Two methods for archive creation are provided:

- **Archive Data**: Creates an archive file and removes data from the active database. By default, all data that is older than the Active Record retention period (in Security Setup) is archived. The user may select a different ending date and time range, so long as this range is prior to the record retention setting (in the system security setup window).

- **Export Archive**: Creates an archive file but does not remove the selected data from the active database. The user may specify both starting and ending date and time ranges.

Once the desired method is selected, click the Next button and choose a data and time range for the archive. Click the Finish button to create the archive. A dialog will inquire as to where the file should be saved.

Archive files contain security elements and digital signatures to assure regulatory compliance when printing a report from an archive.

Notice: The archive file will contain a copy of the currently selected report template; it may optionally contain copies of all the templates (option choice is given during the creation process).

By default, standard data archives will be saved in "C:\Documents and Settings\All Users\Application Data\DTPro\DataArchive". This is a system folder that may be hidden, therefore, it may be preferable to save Export Archives to a different folder.

By default, the file name of an archive begins with "DTArch" and contains date codes indicating the data range (day / month / year format) The file extension of an archive is ".ZIP".

11.1.2 Viewing an Archive

Select the View Archive option and click "Next" button. A list of available archive files will be displayed. If the archives were not saved at the default location (mentioned above in Section 11.1.1), it will be necessary to browse to the folder where the archive(s) exists. Select the desired archive and click "Finish" button.

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. The archive file can then be viewed through the Data View window (Expand Reports, click Historical Data).

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 the provided button. The connection to the standard database will be resumed.

While viewing an archive, Logger functions, Radio reception and some other system configuration items will not be available (any function that might require recording data in the standard database).

Note: Archive creation and access are audited events.

11.1.3 Exporting Data

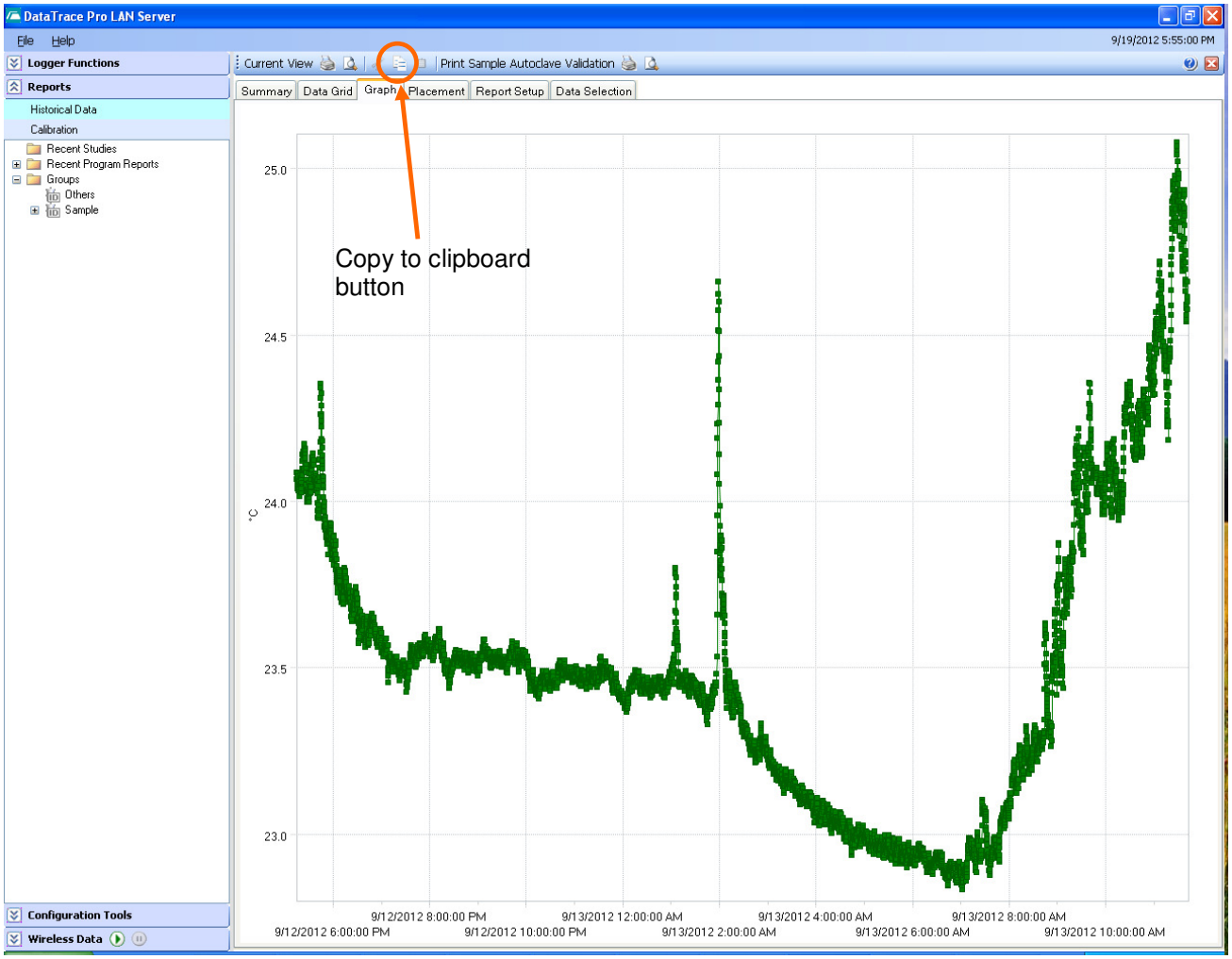
Warning: when data is copied or exported for use by other applications, the subsequent work output from these applications is not likely to be 21 CFR Part 11 compliant.

Exporting data will create a file of the data suitable for importing into other applications or e-mailing. Supported export formats are: comma separated value (*.csv), tab separated (*.tab), text file (*.txt) and DPT (old DTW style single logger format included for backward compatibility).

To export data, launch the Database Utilities Wizard, then select the desired export file format. Then click the “Next” button and follow the instructions of the wizard. The data selection process is similar to selecting data for reports. When all selections have been made, click the “Finish” button.

11.1.4 Exporting Data by Copy and Paste

The easiest way to export data is by copying data to the Windows clipboard and pasting into the desired application or file. The data copied from the data grids in the Data View, Read or Real Time View windows may be directly pasted into a spreadsheet application. Graphs and Placement views can also be copied and pasted into applications or files that accept image type information.



Notes:

- *The "Copy to clipboard" button is typically located near the upper left corner of the windows that support a copy function.*
- *Copying data is not a restricted activity and is not an audited event.*
- *DataTrace Pro does not allow data copied from external sources to be pasted into its environment.*

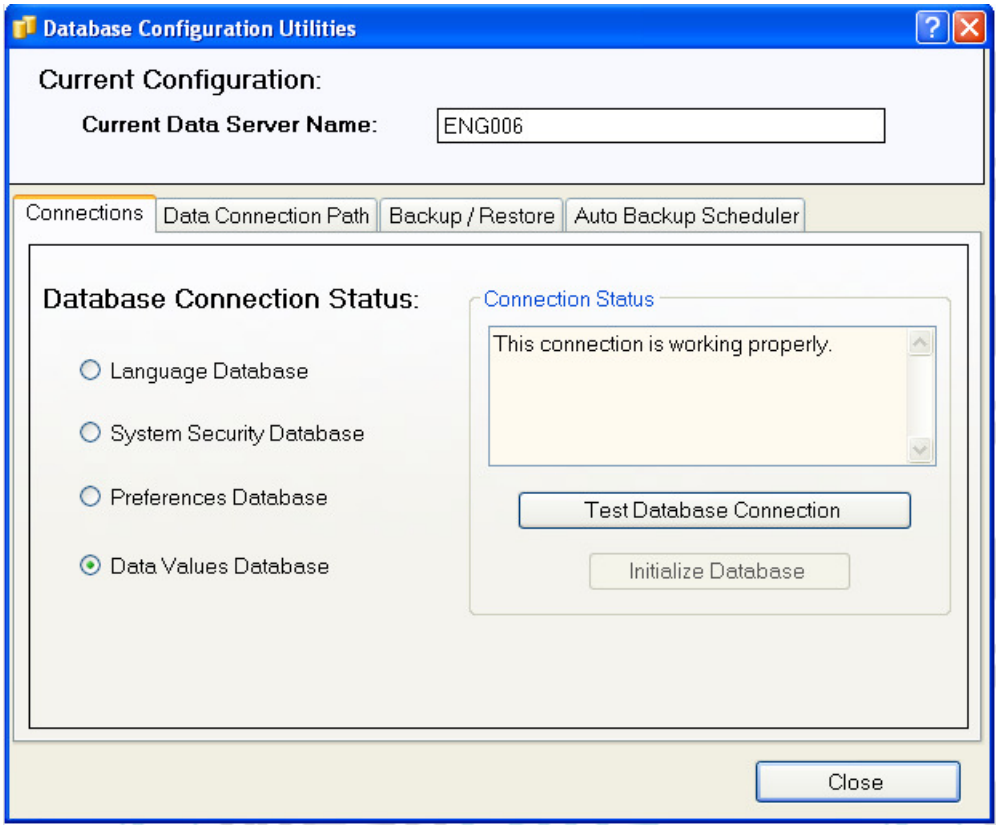
11.2 Database Configuration Utilities

The Database Configuration Utility is accessed by expanding Configuration Tools and clicking the "Database Configuration" button. This 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.

Note:

- *The Database Configuration utility is not available while RF data reception is active.*

See screenshot for a quick glance at the Database Configuration Utilities window:



Current Data Server Name: This box displays the name of the computer where data and security information is being stored. This may be the name of the local computer or that of a network server.

The utility contains four tabs which are:

11.2.1 Connections

The DataTrace Pro database is actually composed of four distinct databases which are shown in this tab. The status of the connection to each of these may be reviewed, tested or initialized. The specific database functions are:

- **Language**: Provides translation and localization services; it is local machine specific.
- **System Security**: Contains all security related settings and information (including the audit trail); it is located on the computer indicated by the Current Data Server Name.
- **Preferences**: Contains user preferences such as units of measure, graph line colors, report templates, etc.; it is local machine specific.
- **Data Values**: Contains logged data, calibration information, group and alarm definitions, etc.; it is located on the computer indicated by 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.

Test Database Connection button: select a database and click this button to refresh the connection status text box. The test routine may resolve a problem, or, may indicate that initialization is required.

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

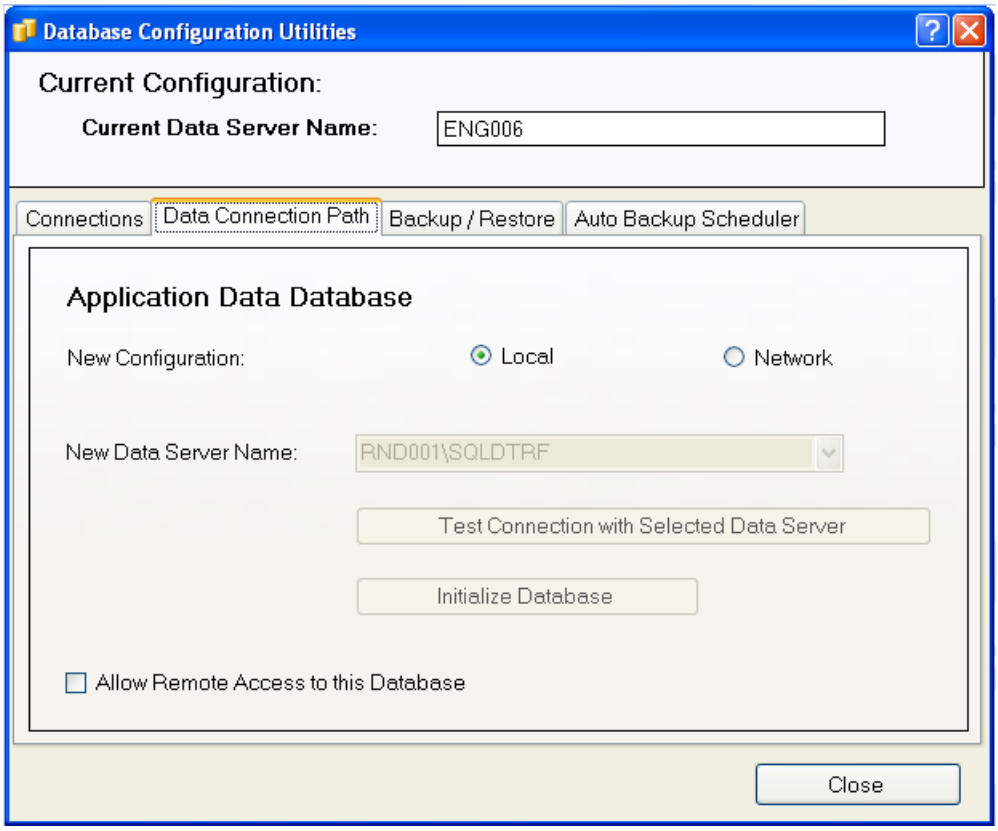
Notes:

- *Connection Testing is not normally necessary but is required for a formal Installation Qualification (IQ).*

- *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, use the Section 8.4.1: Report Manager to export the desired template and import it on the new computer.*

11.2.2 Data Connection Path

This tab allows the system administrator to configure the physical location of the Data Value and System Security databases and set the sharing option.



- **Local**: select this option for local computer data and security information storage. This is the default setting.
- **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.
- **Allow Remote Access**: available only if the Local option has been selected and only for the DT Pro LAN Server edition. Check this box to expose 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.

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** must be set before remote computers can link to it:

- **Test Connection**: When switching between Local or Network, or between different remote connections, always **Test the Connection** with the selected Data Server.

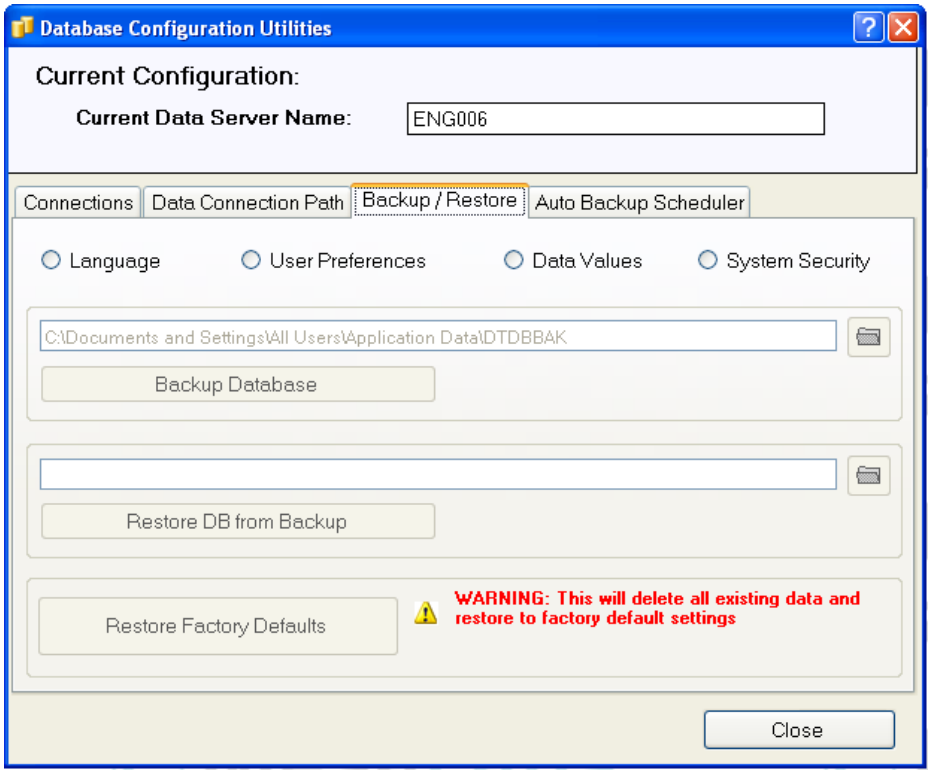
- **Initialize Database**: Use this button if the connection test result indicates it is needed.

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 a read-only password for this access.*

11.2.3 Backup / Restore



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 remote computer. The procedures are executed individually for each of the four databases as needed based on the selection made.

Company policies or regulations may require data backup. It may be difficult to backup 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 (see Auto Backup Scheduler below).

The Restore items are typically used only in cases of database damage or corruption, and preferably only after consultation with Mesa Laboratories, Inc personnel.

- **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.

- **Restore DB from Backup**: Use the folder button to locate an appropriate backup file and click the Restore button. Data that is newer than the backup creation date will be lost!
- **Restore Factory Defaults**: Use the folder button to locate the backup file. Click the Restore button. All existing data will be lost!

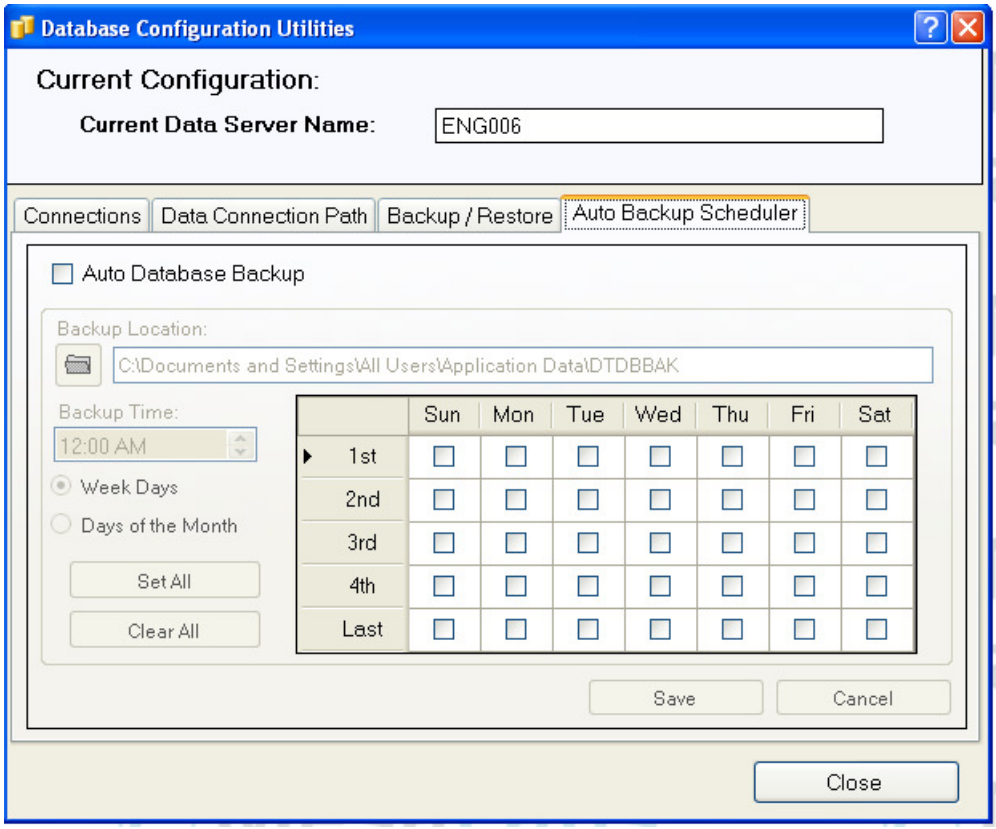
The severity of data loss associated with restoring from a backup or factory defaults, and implications on data retention or 21 CFR Part 11 compliance are dependant on the selected database. Restoring the Language or User Preference has minimal implications (possibly only require resetting a few preferences); 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 procedures dictate the periodic creation of backups, and a DT Pro software upgrade is performed, backups should be performed immediately after the upgrade so as to assure backup file compatibility.

For critical applications, it is preferable that the data and security databases reside on a remote server that has automated system backups implemented by IT department procedures.

Mesa Laboratories, Inc. may add support for new languages. In that event, direction will be given on how to use these tools (applied to the Language database) in order to implement support for the new language.

11.2.4 Auto Backup Scheduler



DT Pro may be configured to automatically perform a complete database backup at a periodic schedule. This tab allows the administrator to enable or disable this feature using the top left check box. If Auto Backup is enabled, the Data, Security and Setup 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. They are in *.zip format, and may themselves be secured (e.g. tape backup) or copied to different media.

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

- **Backup Location**: Enter a path or browse to the folder where the backup files will be saved.
- **Backup Time**: Select the time of day that the backup will be performed. This should typically be some time when system usage is expected to be low (e.g. near midnight).
- **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 is desired.
- **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 (regardless the actual date)

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 schedules backup date and time will be displayed at the lower left corner.

Notes:

- *The backup process may require from one to a few minutes. During this time RF data reception is disabled. While any lost data will be recovered, it is preferable to coordinate the backup time with the data logging and transmitting interval, that is, select a backup time during which logger RF communication is not expected.*

- *The backup process will only occur if DT Pro is running.*

Chapter 12: Troubleshooting

This chapter provides detailed information on several troubleshooting topics.

12.1 Radio Data Reception Problems

The most common cause for reception problems is that the environment is less than ideal or the transmission distance is too great. If the following typical problem causes do not resolve the problem, the addition of a router or repeater may be indicated (especially if the problem disappears when the problematic logger is moved to a different or closer location).

Familiarity with the radio operating parameters is recommended when diagnosing radio problems: see Radio and Network Details section of the DT Pro Help File for more information.

Diagnostic measurements (radio signal strength and seconds since last communication) can be viewed on the right side of the Real Time View window.

12.1.1 Data Is Received but not Logged or Graphed

- Data logging has been disabled for the logger. Expand Configuration Tools, find the logger in question within the browser, and use the browser options menu to re-enable it.
- Logger has been out of communication with the system for an extended period of time. If the logger's internal time is wrong by more than one data logging interval, its received data is not logged. The system will synchronize the logger, and once this occurs, logging / graphing will be available, and any missed data will be retrieved. *Does not apply to environmental monitors.*
- The Graph is not set to plot the data type being received (for example, the graph is set to Plot RH only, but only temperature Loggers are in use).
- The Graph will be blank if less than 3 rows of data are available. This can occur at start up, especially with longer data transmission intervals.
- The Data View (reports) graph does not automatically update when data is received, use the Real Time view graph for this.
- When creating a report, data compression or interval reduction can result in the inadvertent omission of data when mixed data logging intervals exist within the group of logger data being viewed.

12.1.2 Data Reception is Intermittent

- MPRF Loggers are attempting to transmit simultaneously. This may occur when Loggers are programmed using a channel on which there already is a group of Loggers transmitting, or on a computer different than the one receiving data. DT Pro will take corrective action, but this may require a significant amount of time (dependant on how bad the communications are).
- The Loggers are using Fast Mode; if the number of MPRF Loggers 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 Loggers). This is normal and any missing data points are eventually retrieved.
- If some data points are missed, the DT Pro will normally retrieve these missed points.
- Radio data reception may be intermittent (or cease completely) when the temperature of the body of a logger is changing rapidly or the temperature of the Logger is greater than 125° C or less than -40° C.
- Radio data reception may be intermittent (or cease completely) if the body of the logger is not at the same temperature as the sensor (e.g. the sensor is measuring a very high or very low temperature through a port or door, while the body is near ambient temperature or protected by a thermal barrier). Normally, the measured temperature is used for small RF frequency temperature corrections. If the logger body will not be at the sensor temperature, use the "Body at ambient" option when programming the logger. *Does not apply to environmental monitors.*

- Reception may be intermittent during Report Creation, Printing, Programming, Reading, or other user activities which require significant computational resources. Data is eventually recovered.
- Reception may be intermittent if the system's mesh network (routers) is configuring itself. This can occur at start up if the host receiver had been powered down. Data is eventually recovered.

12.1.3 No Data is Received

- The Loggers were not programmed for radio transmission. This can also occur if more Loggers are programmed than the Number of Loggers setting in the Program MPRF Radio options screen (the Program Logger Wizard will issue a warning if this condition occurs).
- Normally, Loggers begin transmitting data within two to three intervals after programming. If Fast Mode was used (the number of MPRF Loggers is close to or exceeds the logging interval), the Loggers will not begin transmitting until the programmed start time arrives.
- The Loggers were programmed for a different channel than the Host receiver. The reception channel for the host can be seen by right clicking on the Host's icon and selecting "Properties", or can be changed from within the Test Logger window (Tools menu)
- The Host receiver is not functional. A MPRF Interface consists of two distinct circuits; the Radio circuit and the IR (infra-red) communications circuit. The ability to program or read Loggers is not an indication that the radio circuit is working. In the Test window, the "Test Host" function checks that the Radio circuit is communicating, but does not check that the radio Receiver is actually functional.
- The communications port for the MPRF Interface is not properly set or the USB Interface drivers are not properly installed. If this is the problem, it would also be impossible to program, read or test a logger
- The MPRF Logger (or a Repeater) has reset, which can be confirmed by performing a Test Logger. The Logger may need a new battery.
- The MPRF Logger is too close to the Host Receiver (or is in the Interface). When checking radio communications, the two devices should be at least 6 inches apart (approximately one wavelength).
- Logger body or sensor temperature is greater than 125° C or less than -40° C (see previous and next section).

12.1.4 Radio Reset (Data Reception Stopped)

Radio transmission requires much more power than data logging. When a logger has a battery with insufficient power to transmit, it will cease all RF transmissions, but continue data logging. A power reset will not occur, but the radio reset condition will be identified when the logger is read (a battery replacement recommendation is made).

This condition can also occur when a logger is used in cryogenic environments (where battery performance is severely degraded); radio reception **will not** resume once the logger is warmed and more power is available!

12.1.5 Environment and Distance

- The radio is specified to transmit data at least 100 feet line-of-sight, newer models may transmit up to 500 feet. Intervening walls, machinery or other obstructions will reduce the distance data can be transmitted.
- Radio will not go through metals (Faraday's Law). Transmission of data from a metal chamber, oven, autoclave or freezer requires there be some non-metallic path for the radio signals. A rubber door gasket is usually sufficient, but the signal will be significantly attenuated (weakened). It may be necessary to place the Host receiver, a Router, or a Repeater quite close to this door (or radio path).
- Whenever possible, avoid placing loggers or mounting monitors directly on metallic surfaces. This can limit distance and create "blind spots" for the reception or transmission of signals from locations directly behind the metal surface.
- The Logger's radio network is tolerant of other devices using the same frequency or channel; however, performance may improve by using a different channel. If it is known that other equipment in the vicinity is using a Zigbee channel, avoid using that one for DataTrace equipment.

- The LEDs on loggers and monitors may be used to diagnose distance problems; see Radio Function LED Indicators in the DT Pro Help File for more information.

12.2 Channel Selection

The Channel Number value determines the Zigbee channel the logger radio will use to transmit data. Allowed values are 0 through 14. MPRF Loggers use a modified Zigbee protocol in the ISM (Industrial, Scientific and Medical) 2.4GHz band. Transmission protocol is compatible with IEEE Standard 802.15.4. The protocol detects data corruption and disallows it as a valid reception. The FCC certifications for MPRF Loggers require that the Logger does not transmit if it detects some other transmission in progress, therefore, it is preferable to use a channel that in generally clear (not used by other devices).

If there are other (non Mesa Laboratory) Zigbee devices in use (which will typically also have a configurable channel number), it is preferable to use a different channel. Wi-Fi systems also use the ISM band. If it is known that a Wi-Fi or data routing system is configured for a lower channel, use higher channels for the loggers (or vice versa).

Some automatic RF control functions (e.g. RF commands to change interval or retrieve missed RF data) occur both on the selected channel and also on the next higher channel (or on channel 0 if the selected channel was 14). When allocating different channels to different groups of loggers, it is preferable to have these groups use channels that are not sequential, for example, only use even channels. Conforming to this guideline is more important when repeaters or environmental monitors are in use.

Lower valued channels have slightly higher power capability (and longer range) than higher valued channels.

If there are other MPRF users or departments, and it is desired to keep distinctly different data sets, each user or department should use a distinct channel.

The RF domain name, configured in Chapter 2: System Setup, is used to generate an encrypted control key which is loaded in RF capable devices (when loggers are programmed, when environmental monitors or repeaters are captured, or when RF host interfaces are started). RF control functions and data reception can occur only when the domain control key matches the system, even if RF transmissions occur on the same RF channel. If it is desired to program loggers on one computer, and receive RF data on another one, both systems must be configured with the same RF domain and use the same channel.

In order for successful RF communications to occur, the Host receiver, loggers, environmental monitors or repeaters must be configured or programmed for the same channel. For loggers, this occurs when they are programmed. For environmental monitors or repeaters, the channel is set when the device is captured. The channel of the host receiver is set when logger are programmed with the "Program Host" option enabled. Host channel can also be viewed or changed from the Test and Calibration window (tools menu), or from Configuration Tools (expand network routers, select the host serial number and then right click for the pop up menu, select Host Channel).

12.3 Interface Communication Problems

The following information pertains to communications with the Logger using the Interface. To troubleshoot radio related issues, see Section 12.1 Radio Data Reception Troubleshooting above.

12.3.1 No communications with any logger.

A problem with the Interface, computer, or the system setup is indicated.

The Logger Type is not set right. In the Program, Read or Test windows the type of Logger (MPRF or MPIII) must be set to match the device being processed

Avoid placing the Interface in direct sunlight or other a bright light as this can cause IR (infra-red) interference and lead to communications problems.

The USB driver was not properly installed. See Section 12.4: USB Interface Troubleshooting.

A computer operating system problem can occur where the PC has lost its recognition of a USB device. With all of the DTRF windows closed, try unplugging the Interface and then plug it back in.

12.3.2 No communication with one (or a few) Loggers, others communicate as expected

A problem with the Logger is normally indicated, but the interface might have a problem (see next heading).

Communications for MPRF and MPIII Logger are optical. Any stickers or markings placed on the Logger body may obstruct the communications. The Logger and/or Interface may need to be cleaned.

The Logger is hot, or, the Logger is cooling too rapidly. It is good practice to allow the Loggers body to equilibrate to room temperature before attempting to read it.

The Loggers Battery may be dead or too weak to communicate. Try replacing it (see Battery Replacement Procedures in the DT Pro Help File for more information). Note: The battery gauge is only an estimate! See Section 12.7: Battery Gauge for details.

Inspect the inside of the Logger. If fluid or corrosion is observable, the Logger will require factory service.

12.3.3 Intermittent Communications

As in interface ages, its optical communications performance may degrade. As a logger ages, its optical communications performance may degrade. These effects usually require years to manifest. Within any group of loggers, some will have slightly stronger optical communication performance than others (even though all the loggers may be in tolerance). When the performance of the interface is poor, a situation can arise where communication is possible with the slightly stronger loggers, but not with the slightly weaker ones. The tendency in this case is to diagnose a logger problem, but the problem is actually with the interface.

The interface may be weak because the optical tube requires cleaning. Wipe out the interface with a clean, lint free and non-abrasive cloth. With care, the tube can be removed (by using one finger and slowly twisting and pulling from within the tube) and inspected: it should be quite clear and transparent (not cloudy).

Whenever a communications with a group of loggers is intermittent, try using a different interface. If communications problems persist after logger service, the interface should be serviced or replaced.

12.4 USB Interface Troubleshooting

The following pictures are from a Windows XP system. There may be some differences when using other operating systems.

If a Logger can be properly tested and communicated with, but the problem is that the Host will not allow configuration or receive radio data, the problem is not with driver installation and it is most likely the host radio hardware is damaged.

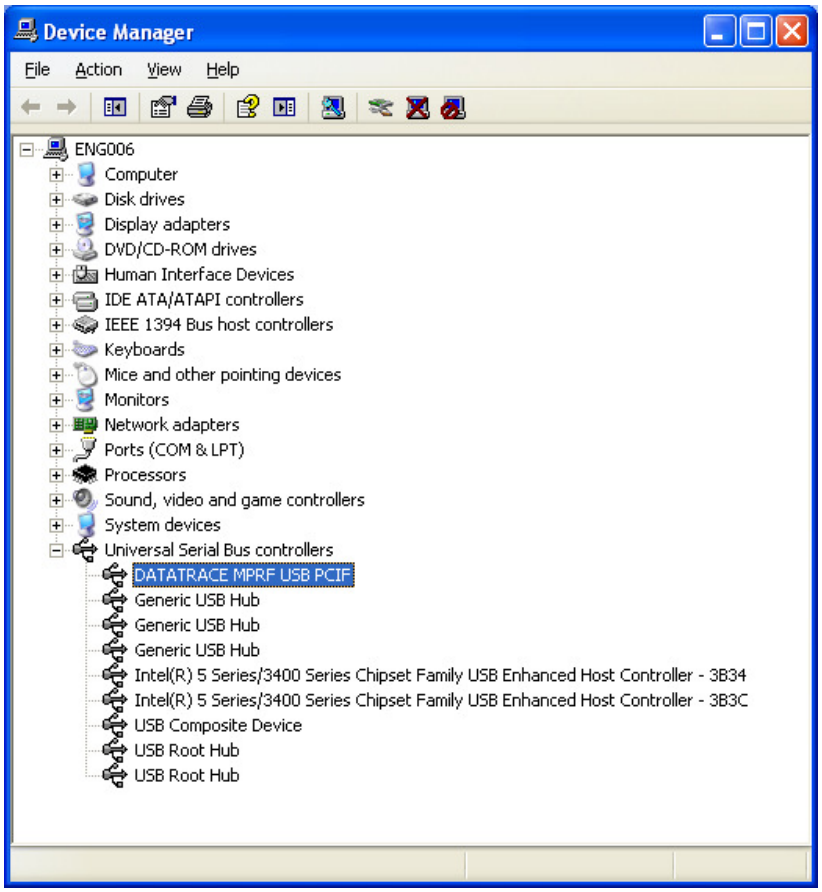
Communications may be improved by cleaning the clear acrylic tube the Loggers sit in; wipe with a dry or slightly damp soft paper or cloth. Do NOT get the inside of the Interface wet!

In some cases communications may be achieved by turning the Logger within the Interface. If this procedure corrects the communication difficulties, a portion of the IR communications transmitter or receiver circuit is damaged and should be repaired at the factory.

12.4.1 Check the USB Driver

Determination of proper USB Driver Installation is made by using Windows' Device Manager Utility. Access your Windows' Device Manager Utility.

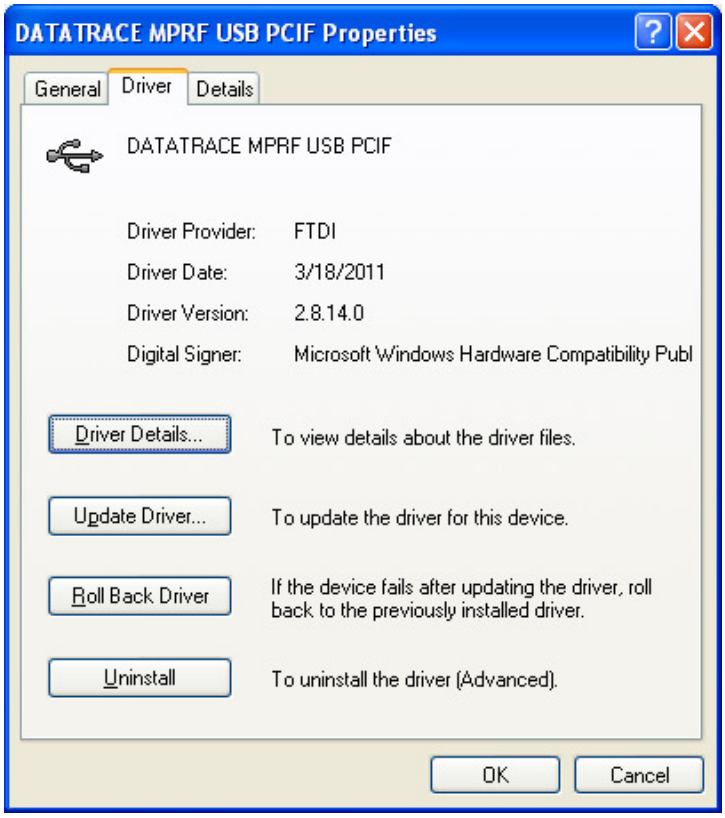
The Device Manager window will open. With only your MPRF USB Interface plugged in, expand the Ports "(COM and LPT)" and "Universal Serial Bus Controllers" items as shown below.



Note that there are no Communications Ports identified as DataTrace USB Ports (as was the case with earlier DTW USB Drivers); DataTrace should appear only in the USB controllers section. If it does appear as a COM port, see below.

Check the USB Driver Version by right clicking on the DataTrace PCIF item and selecting Properties. Click the "Driver" tab. DT Pro requires Driver version 2.2.4.0 dated 6/27/07 or newer, as shown below.

Notice: USB Driver version 2.8.14.0, dated 3/18/2011, or newer, is required for 64 bit Windows 7 operating systems.



If the driver version is older, Place the DT Pro CD in the computer and click the Update Driver button. If DT Pro was installed via internet download, a copy of USB drivers is available in C:\Program Files\DataTrace Pro\USB Drivers

Click the Advanced Tab and verify the VCP setting. This should be unchecked.

If the VCP setting was checked, it is the reason there was a Communication Port displayed in the Ports (COM & LPT) section. After unchecking it, unplug your USB Interface, wait a moment for it to disappear from the Device Manager screen, and plug it back in. Verify a COM Port does not appear.

If New Hardware is not detected or the balloon does not indicate a DataTrace device:

The Interface hardware may be damaged.
The Interface may have been installed using a non-DataTrace driver. Use and watch the Device Manager while plugging in and unplugging the Interface and observing if another device type appears. If so delete / uninstall the non-DataTrace USB driver, reboot and install the DataTrace USB drivers.

12.5 Erratic or Inaccurate Data

Gross temperature measurement errors are usually indicative of hardware failure and will require factory service for the Logger. Relative Humidity measurement error can commonly be corrected in the field (if the temperature measurement is functioning properly. Small accuracy problems can be corrected by field calibration if desired and if the Logger model supports field calibration.

Any evaluation of Logger accuracy should take into account the response time of the Logger, the accuracy of the reference measurement the Logger will be compared to, the stability of the reference environment, and the Logger's specified operating range.

12.5.1 Common causes for % RH measurement error

- The RH sensor is loose or making intermittent contact; it should fit snugly. If it is loose, remove the sensor, use needle nose pliers or tweezers to put a small bend (about 30° angle) in the legs of the sensor and re-insert it.
- The RH sensor was exposed to a condensing environment. Allow the sensor to dry off. Use the Test Logger function to confirm good measurements prior to process use.
- The RH sensor has been damaged by repetitive exposure to a corrosive environment such as Ethylene Oxide. When a Logger is used for RH monitoring during EO sterilization, the RH sensor may need to be replaced or re-calibrated frequently (model and sensor dependant).
- Relative Humidity is dependent on temperature. When the temperature is changing rapidly, there can be significant difference between the RH inside the Logger's protective cover and the outside environment because of the lag in temperature.
- An inaccurate or unstable RH reference was used during a field calibration.

12.5.2 Causes for Temperature measurement error

- The temperature sensor or other Logger hardware is damaged and will require factory service.
- An inaccurate or unstable reference was used during a field calibration.

12.5.3 Missing Data

With some types of Loggers a hardware problem can occur which causes the Logger's clock to stop. This condition is noticeable when there are fewer data points logged than expected or as compared with other Loggers that where in the same process, and usually occurs at high temperatures. Some possible causes are:

- The Logger hardware is damaged and requires factory service.
- The Logger body was exposed to a temperature greater than 140° C during the process (clock stoppage occurs around 145°C with some older MPIII types).
- The Logger's battery is low (see Section 12.7: Battery Gauge for details), occurs mostly with older MPIII Pressure Loggers.
- There is an interfering IR communications emitter: this has been observed only one time - in a warm room, the presence of an amber emergency light (IR emitter) adversely affected loggers (caused continuous communications interrupts and disrupted data logging). The solution was to place dark tape over the communications windows while validating this room.

12.5.4 MPIII Pressure Inaccurate Data

Some older MPIII Pressure Loggers will measure pressure inaccurately when the battery is very low or weak. The probability of this problem occurring increases when using very rapid logging rates (<10 seconds). The magnitude of the error is typically 5 to 10 PSIA.

12.6 Logger Reset

A Logger Reset condition occurs when power to the Logger Circuit is interrupted, the Logger battery is too weak to perform the required function(s), the circuit or sensor is damaged, or more rarely, may occur due to an electrostatic discharge event. If a Logger is logging data and a reset occurs, it will stop logging, and when read, data can only be recovered up to the point the reset occurred.

12.6.1 Common causes for a Logger Reset

- Changing a battery, or simply removing the battery cover.
- The battery springs (MPIII) are missing, contact to battery is intermittent.
- The battery contacts are corroded, usually quite noticeable by visual inspection.

- The battery is actually lower than the battery gauge indicates, the **battery gauge is only an estimate;** the logging interval may be too fast given the environment; see Section 12.7: Battery Gauge for details.
- The Logger circuit is damaged and consuming too much energy. This condition may be inferred if it is possible to read Logger data and erratic or anomalous data is observed; indicating a sensor short circuit (with consequent excessive battery depletion).
- The battery contacts or circuit have been damaged by use of a non-approved battery, improper battery installation, mechanical shock or other physical damage; when a Logger is shaken, there should be no rattling noise apparent (indicating intermittent battery contact).
- While all Logger designs undergo ESD (Electro-Static Discharge) testing and performance certification, a static electricity spark may on occasion cause a reset.
- The Logger was programmed to transmit radio data while exposed to ultra-low temperatures (less than -40° C). At very low temperatures the battery might not be capable of providing sufficient energy for radio operation.

12.7 Battery Gauge

This information may be applicable when diagnosing Logger Reset or communications problems.

When a logger is programmed, read, or radio data is received, an estimate of the energy remaining in the battery is made and displayed as a percentage.

The battery usage display is an estimate only! The chemistry of the lithium batteries used by Loggers is such that an accurate battery % remaining cannot be directly measured or inferred from a battery voltage measurement.

The estimate of Battery % remaining is based on the date the battery was installed, how many measurements have been made and how many communication events have occurred. This information is stored within loggers or repeaters. Using this information an approximation can be made as to how much energy has been removed from the battery and how much energy remains.

When a new battery is installed, the reset event is detected and the user will be asked if a new battery was installed. Answering "Yes" causes a new battery date to be uploaded to the Logger and the number of measurements and communication events are reset to zero.

If the original battery is re-installed, and the battery information is reset as if new, the battery gauge will erroneously indicate a full battery. Likewise, should an unexpected reset occur (e.g. from a static spark), one should not answer "Yes" to the new battery inquiry.

12.7.1 Battery Gauge Inaccuracies

Other than inadvertently resetting the battery information, the battery gauge may not be accurate due to the way the Logger is used or the environment it is used in. The approximation algorithms do make some allowances for the following effects, but in some cases battery gauge inaccuracy can be significant.

Battery performance is significantly degraded at low temperatures. While the gauge may in fact be accurate, at very low temperatures the ability of the battery to provide energy rapidly is degraded. If the Logger is used with a short interval (typically less than 10 or 15 seconds), the Logger's demand may exceed the batteries ability to supply energy and a Reset will occur. The applies especially to MPRF Loggers performing a Radio Transmission at very low temperatures (less than -40° C); In such conditions it is advised to limit the MPRF Logger interval to 1 minute or greater.

The Logger circuit uses more energy at high temperatures, even during storage. This problem is also aggravated by usage with fast logging intervals, and may be especially noticeable in MPIII Pressure type Loggers used at greater than 125°C (at rapid logging intervals).

If it is observed that Logger Reset problems are usually corrected by the use of a new battery, then it may be necessary to take the above effect into account, establish a typical battery threshold and replace batteries when the gauge indicates the established threshold.

The need to replace batteries more often than indicated could also be a problem in the circuitry of the Logger, especially if the replacement rate is excessive, for example, needing to replace batteries while the gauge indicates 80 % remaining would most likely be caused by a hardware problem.

12.8 Database Troubleshooting

The Database Configuration Utility is accessed by expanding Configuration Tools and clicking the Database Configuration button. This 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.

If these tools cannot correct problems, it is recommended to contact Mesa Laboratories, Inc. for assistance.

The most common problem involves user permissions to create folders during installation or read / write to files after installation.

12.8.1 Advanced Details

The following information is given for those with some experience with SQL databases or IT issues.

- The physical location of the database files, after installation, is normally C:\Documents and Settings\All Users\Application Data\DT Pro. The user that installs DT Pro must have full access rights to these directories (with the ability to crate new folders). All DT Pro users must have read /right access to the folders in the DT Pro directory (both on their own local computer and for the remote computer if Network connections are is in effect). Each database resides in its own folder (.mdf and .ldf files).
- The factory default (schemas) are located in the installation folder (normally C:\Program Files\DTPro\Schema).
- SQL Manager express, a free utility for diagnosing SQL database connection issues, is included on the DT Pro installation CD.

12.9 Reporting Software Problems

In the event of unresolved problems with the DataTrace Pro Software, please feel free to contact us. Having the following information can be helpful or may be requested:

- Description of the Problem.
- Window or screen at which the problem occurs.
- DT Pro Software Revision (Help menu > About).
- Logger Type(s) in use.
- Computer Type.
- Computer Operating System.
- Depending on the problem, a Logger Diagnostic Report may be needed (from Test and Calibration window)
- Depending on the problem, the contents of the ErrLog.txt file located in DT Pro's working directory (Typically: C:\Program Files\DataTrace Pro may be needed.

Contact Information

Mesa Laboratories, Inc
12100 W. 6th Ave.
Lakewood, CO 80228 USA

Tel: (303) 987-8000
Fax: (303) 987-8989
www.mesalabs.com