

STANDARD OPERATING PROCEDURE For the DataTrace[®] SYSTEM

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1. Purpose

To provide an operational procedure that describes the setup and use of the DataTrace[®] system.

2. Scope

The Standard Operating Procedure for the DataTrace[®] system provides:

- Safety information
- A listing of DataTrace[®] system equipment
- A description of the DataTrace[®] system
- Information on establishing security
- Instructions for using the DataTrace[®] system

3. Safety

The following safety considerations and precautions will be observed during the use of the DataTrace[®] system.

3.1. DataTrace[®] Tracers

- Handle the DataTrace[®] components carefully, they are precision instruments.
- DataTrace[®] equipment is rated intrinsically safe. Any substitution of Tracer components with non-DataTrace[®] approved components could compromise that rating.
- Do not heat MPIII Tracers above 140°C; FRB Standard Temp Tracers above 150°C; and FRB LoTemp Tracers above 85°C.
- Clean the Tracers and allow them to return to ambient temperature before attempting to communicate through the PC Interface.
- To maintain the seal for all Tracers, replace and properly lubricate the new O-ring, whenever the Tracer is opened. Ensure that the Tracer cover is properly secured before using.
- Tracers should be kept in their Storage Modules when not in use which protects the Tracers from damage. A Tracer's probe is its most vulnerable component which can be bent, nicked, dinged, and broken if not protected properly.
- Use a mild detergent and warm water to clean the Tracers between tasks. If non-water soluble residue remains on the Tracer, use an appropriate solvent followed immediately by a warm water and detergent bath. Stubborn materials can be removed from the Tracers with plastic scrubbing pads or soft copper wool dipped in alcohol.
- Periodically check the DataTrace[®] Tracers against a known reference standard such as a National Institute of Standards and Technology (NIST) standard to verify their calibration. The total system uncertainty should not be more than 25% of the accuracy desired for the calibration. (Reference: ANSI Z540-1-1994 10.2b.).
- Do not use any wrenches, pliers, vices, or other mechanical means to screw on or tighten the Tracer battery cover. The Tracer gripper is adequate to close and seal the battery compartment if all procedures are followed. Using any other device may damage the Tracer and make it unusable.

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3.2. Batteries

- DataTrace[®] batteries for the FRB type Tracers are field replaceable 3.6 Volt dc (Standard Temp Tracer) or 3.9 Volt dc (LoTemp Tracer), Lithium Thionyl Chloride batteries.
- DataTrace[®] batteries for the MPIII type Tracers are field replaceable 3.0 Volt dc Carbon Monofluoride Lithium batteries.
- The batteries used in the DataTrace[®] equipment are specially designed for this application. USE ONLY BATTERIES SUPPLIED BY DataTrace[®]. Trying to use any other lithium battery will void the equipment warranty and could damage DataTrace[®] equipment.
- Caution needs to be paid to the handling, storage, and disposal procedures of Lithium batteries. Follow these instructions completely. Variations to this procedure could damage the battery, or DataTrace[®] equipment, and/or cause operator injury.
- Do not attempt to recharge, disassemble, or incinerate DataTrace[®] batteries.
- Do not heat MPIII batteries above 140°C; FRB Standard Temp batteries above 150°C (also used in FRB HiTemp Tracers); and FRB LoTemp batteries above 85°C.
- Note the warning labels on the batteries or battery trays.
- The battery should be replaced by a qualified technician in an anti-static and non-hazardous environment.
- Disposal of spent batteries must comply with local, state, and federal regulations.

4. Equipment

- DataTrace[®] PC Interface system includes the Interface module, serial cable, and DataTrace[®] for Windows software.
- Multiple DataTrace[®] Tracers.
- A computer with minimum requirements as defined in section 6.2.1.

5. Reference

The DataTrace[®] Operator Manual (124766-001 Rev. B) is installed on the target computer during the normal installation process. It is also accessible on the DataTrace[®] for Windows CD.

6. DataTrace[®] System

Accurate knowledge of processing times and process parameters provides increased confidence that products and processes satisfy the operational requirements and meet any applicable regulatory requirements. The DataTrace[®] system collects process data with minimal disruption to the process because the Tracers can be placed directly into the target application. The DataTrace[®] for Windows (DTW) software provides the interface for computer communication to program and read Tracers. Following data collection and retrieval, the program can be used to analyze and manage the collected data. The Tracers are completely self-contained sensors.

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6.1. System Description

The DataTrace[®] System is comprised of two primary components. First, is the PC Interface System for programming, reading, and communicating with the Tracers, and, second, are the Tracers (MICROPACK III[™], FRB MICROPACK[™], MICROPACK[™] and FLATPACK[™]) which are miniaturized data recording devices.

The DataTrace[®] PC Interface and Tracers together collect and create permanent records of a process. The Tracer is designed to travel with products inside containers as these products proceed through a processing environment. This vital information is obtained without depending upon external connections; the Tracers are completely self-contained sensors.

The Tracers take and store up to 16,000 data samples during any programmed cycle. By following the instructions displayed on the computer, the Tracer is programmed to capture the required information. Place the Tracer in the process. When the run is completed, remove the Tracer from the process, clean it off, then reinsert it in the Interface Module and recover the collected data. Data can be reviewed in tabular or graphical form. The Tracer can then be reprogrammed for its next assignment.

Store the DataTrace System in an area where the ambient temperature remains within the range of 10 to 50 degrees Celsius (50 to 122 degrees Fahrenheit); relative humidity should stay between 0 to 99 percent, non-condensing.

6.2. PC Interface System

MPIII Interface Module:

1. The MPIII Interface receives its operating power through the Serial Port connection or a USB/Serial Adaptor. The USB/Serial Adaptor should be installed on the computer before the DataTrace for Windows program is installed. It is advisable to maintain the connection in order to keep the Interface "charged".

Cleaning procedures for the DataTrace[®] MPIII PC Interface are similar to those for the computer. Refer to the computer's Guide to Operations for information on its care. These same procedures will be sufficient to care for the PC Interface.

Non-MPIII Interface Module:

1. Periodic cleaning of the PC Interface contacts is advisable. Clean all contacts with a cloth or scrubbing pad dipped in Isopropyl Alcohol. The cloth should be damp, not wet, to avoid getting moisture into the PC Interface electronics.

Cleaning procedures for the DataTrace[®] non-MPIII PC Interface are similar to those for the computer. Refer to the computer's Guide to Operations for information on its care. These same procedures will be sufficient to care for the PC Interface.

2. As the 9 volt battery in the interface module nears the end of its life, the "Interface Battery Low" LED will glow red. Replace the battery as soon as possible to avoid disruption of your DataTrace[®] operations. Note that some batteries as they become marginal may not cause the LED to glow initially, it may take awhile. We recommend replacing the 9 volt battery in the interface at least once a year.

6.2.1. DataTrace® for Windows (DTW) Software

SYSTEM REQUIREMENTS:

The DataTrace® for Windows program is designed for use under any Windows 32-bit Operating System, such as, Windows 9x, Windows ME, Windows NT4.0, Windows 2000, or Windows XP. It will not operate in a DOS-only environment.

The following is the minimum system requirements for operating the DataTrace® for Windows program.

- Pentium 133MHz
- 32MB RAM
- 20MB of free hard disk space
- Windows 9x, ME, NT4.0, 2000, XP Operating System
- 1 Free Serial or USB Port (USB Serial Adaptor must be pre-installed)
- 1 CD ROM drive
- 1 Mouse

6.3. Tracers

Maintaining the Tracers and the PC Interface is primarily a matter of applying common sense.

Tracers are designed for harsh environments and the rigors of traveling with products through the process, recording data profiles. The greatest risk to a Tracer is being dropped onto a hard surface. The sensing probe or the electronics could be damaged by the impact.

6.4. Battery Replacement Procedures

MPIII Battery Replacement

This section describes the disassembly, battery installation, and reassembly for the Micropack III (MPIII) Tracer. The Field Replaceable Battery for Micropack III Tracers allows the user to change the Lithium battery of the unit without the necessity of sending the Tracer to the factory.

Note that replacement of the battery does not automatically recalibrate the Tracer. Normal calibration procedures should be instituted to have each Tracer factory calibrated at least once each year or in conformance with your in-house operating procedures.

Materials Needed:

- DataTrace® Micropack III Tracer(s)
- Lithium Batteries (124804-500)
- MPIII Maintenance Kit (124808-500)
- A supply of clean, dry cloths

Micropack III battery replacement is a simple, straight forward procedure. However, care must be taken that these procedures are followed completely to avoid equipment damage or personal injury.

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It is recommend that battery replacement for the MPIII Tracers take place in a dry, well-lit workstation. The best place for this activity would be close to the location that Tracers are stored and programmed and that Tracer batteries are stored.

DO NOT USE ANY WRENCHES, PLIERS, VICES, OR OTHER MECHANICAL MEANS TO LOOSEN OR TIGHTEN THE TRACER BATTERY COVER. THE TRACER GRIPPER AND A COIN PLACED IN THE MPIII COVER GROOVE IS ADEQUATE TO OPEN AND CLOSE THE BATTERY COMPARTMENT. USING ANY OTHER DEVICE MAY DAMAGE THE TRACER AND MAY MAKE REASSEMBLY IMPOSSIBLE.

1. Clean and dry the Tracer body completely. Make sure no process residue remains on the Tracer body that could cause the Tracer to slip from your grasp during the battery change procedure or could contaminate the battery compartment during battery replacement.
2. Grasp the Tracer with the Tracer Gripper in one hand, clasping the base (probe end) firmly. With your other hand, twist the battery cover counterclockwise. Use a coin in the cover's slot, if necessary.
3. Once loosened, remove the Gripper and the battery cover will unscrew easily.
4. Remove the old battery by turning the case over until it falls out.
5. Dispose of the battery appropriately per local regulations. **DO NOT TRY TO RECHARGE, DISASSEMBLE, OR INCINERATE THE BATTERY.**
6. Examine the battery compartment for any signs of contamination, and make sure that the springs located in the cover and inside the battery compartment are in place. If one of the springs has fallen out, reinsert it.
7. Examine the threads of both the battery cover and Tracer body for damage and cleanliness. If the threads show any damage (e.g., cross threading or "burrs"), do not continue with this procedure. Loosely reassemble the Tracer and return it to the factory for repair.
8. If damage is detected or contamination is noted, return the Tracer to the factory for repair.
9. Remove the old O-ring. **DO NOT USE O-RINGS THAT APPEAR DAMAGED. LEAKS COULD RESULT THAT MIGHT DAMAGE THE TRACER AND/OR SHORTEN BATTERY LIFE.**
10. Clean any residue and grease from the threads and adjacent areas including the O-ring groove on the Tracer body with a clean, lint-free cloth.
11. Before the new O-ring is installed, apply a thin coat of silicone vacuum grease (in the Maintenance Kit) to the O-ring.
 - Use a **very small** amount of grease between your thumb and index finger.
 - Place the O-ring between these two fingers and gently pull the O-ring through the grease until a light coating of grease completely covers the surface of the O-ring. The surface of the O-ring should appear glossy.
8. Carefully place the O-ring in the groove on the cap, centering it in the O-ring groove.

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Always replace the O-ring when the Tracer battery compartment has been opened.

The Tracer is now ready for reassembly with a new battery. We strongly recommended that Tracers are **NOT** left unassembled. Damage to components could occur making the Tracers unusable.

13. Obtain a fresh battery from the battery tray. Do not remove more batteries than necessary.
14. Holding the Tracer cover in one hand and the battery positioned on the palm of the other hand with the "+" side up, place the Tracer cover over the battery. This is the easiest way to correctly position the battery to be placed in the Tracer
15. While holding the battery in position, rotate the Tracer cover/battery so that the Tracer cover threads point upwards. Place the Tracer body squarely over the Tracer cover threads. Begin to screw the cover in a clockwise direction. Be careful to not cross thread the cover on the Tracer body threads. The cover should screw on smoothly and easily until the O-ring becomes engaged.
16. Grasp the Tracer in one hand, clasping the base (probe end) firmly. Then twist the battery cover clockwise until resistance is felt. A coin can be used in the cover's groove to complete the tightening procedure.
17. Never tighten the battery cover more than finger tight. Never use anything to hold the Tracer Case except the Tracer Gripper. Over tightening can cause damage to the Tracer cover threads resulting in possible leakage which may damage the Tracer. The design of the Tracer seal is not dependent on high torque to provide an effective seal.
18. With a clean, dry cloth, wipe away any excess Silicone Vacuum Grease that may have been pressed out during closure. Silicone can become extremely slippery in combination with water and could cause the Tracer to slip and be damaged.

The battery replacement procedure is now complete and Tracer(s) are ready for use. The reassembly procedure, if followed completely, will seal the battery compartment, maintaining the waterproof and pressure-tight seal, as well as the intrinsically safe rating.

Following reassembly of MPIII Tracers, always wait 20 seconds then perform the Test Tracer procedure. This will assure that the battery is functioning properly, the electronics are reset correctly, and the Tracer is initialized. During the Test Tracer procedure, a Battery Change Date will be requested. The program will automatically enter today's date, if instructed.

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FRB Battery Replacement:

Materials Needed:

- DataTrace[®] Micropack Tracer FRB Model(s)
- Lithium Batteries (Standard Temp: 123599-500; LoTemp: 300041-500)
- FRB Maintenance Kit (124717-500)
- A supply of clean, dry cloths

The battery change procedure for the FRB model Micropack is simple and straight forward. However, care must be taken that these procedures are followed completely to avoid equipment damage or personal injury.

We recommend that the disassembly of the DataTrace[®] Tracers take place in a dry, well-lit workstation. The best place for this activity would be close to the location that Tracers are stored and programmed and that Tracer batteries are stored and conditioned.

DO NOT USE ANY WRENCHES, PLIERS, VICES, OR OTHER MECHANICAL MEANS TO LOOSEN OR TIGHTEN THE FRB TRACER BATTERY COVER. THE TRACER GRIPPER IS ADEQUATE TO OPEN AND CLOSE THE BATTERY COMPARTMENT. USING ANY OTHER DEVICE MAY DAMAGE THE TRACER AND MAY MAKE REASSEMBLY IMPOSSIBLE.

1. Clean and dry the Tracer body completely. Make sure no process residue remains on the Tracer body that could cause the Tracer to slip from your grasp during disassembly or could contaminate the battery compartment during battery replacement.
2. Grasp the Tracer with the Tracer Gripper in one hand, clasping the base (probe end) firmly. With your other hand, using the other Gripper, twist the battery cover counterclockwise.
3. Once loosened, remove the Grippers and the battery cover will unscrew easily.
4. Remove the old battery by lifting straight out. Do not twist or turn the battery while removing.
5. Dispose of the battery appropriately per local regulations. **DO NOT TRY TO RECHARGE, DISASSEMBLE, OR INCINERATE THE BATTERY.**
6. Examine the battery compartment for any signs of contamination, pay particular attention to the battery socket area. If any contamination is found, remove it, and clean the area with a dry cloth.
7. Examine the threads of both the battery cover and Tracer body for damage and cleanliness. If the threads show any damage (e.g., cross threading or "burrs"), do not continue with this procedure. Loosely reassemble the Tracer and return it to the factory for repair.
7. Remove the old O-ring. **DO NOT USE O-RINGS THAT APPEAR DAMAGED. LEAKS COULD RESULT THAT MIGHT DAMAGE THE TRACER AND/OR SHORTEN BATTERY LIFE.**

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8. Clean any residue and grease from the threads and adjacent areas including the O-ring groove on the Tracer body with a clean, lint-free cloth.
9. Before the new O-ring is replaced, apply a thin coat of silicone vacuum grease (in Maintenance Kit) to the O-ring.

§ Use a **very small** amount of grease on your thumb and index finger.

§ Place the O-ring between these two fingers and gently pull the O-ring through the grease until a light coating of grease completely covers the surface of the O-ring. The surface of the O-ring should be glossy.

- 10 Carefully place the O-ring in the O-ring groove at the bottom of the Tracer body threads. Avoid dragging the O-ring across the threads, they could cut or nick the O-ring, compromising its sealing capability.

The best method of O-ring installation is to start from the probe side and place one part of the O-ring in the O-ring groove. **Slightly** stretch the O-ring with your fingers to position it completely over the O-ring groove, and then release it.

DO NOT STRETCH THE O-RING ANY MORE THAN NECESSARY. DO NOT DEFORM THE O-RING.

Always replace the O-ring when the Tracer battery compartment has been opened.

The Tracer is now ready to reassemble with a new battery. We strongly recommended that Tracers are **NOT** left unassembled. Damage to components could occur making Tracers unusable.

11. Obtain a fresh, conditioned battery. (See conditioning procedure in the next section.) Verify that the temperature range of the FRB Tracer and battery are matched. Standard Temp batteries are rectangular and can be used in FRB Tracers with a **WHITE** or **RED** ring. LoTemp batteries are coin-shaped and should only be used in Tracers with a **BLUE** ring.

Standard Temp batteries (rectangular) and LoTemp batteries (round) have different pin configurations. The FRB Tracer sockets for Standard Temp and LoTemp Tracers are designed to accommodate only the appropriate batteries. So mixing up batteries and sockets is unlikely.

12. Holding the Tracer in one hand and the battery in the other, align the battery pins in the sockets on the Tracer.
13. Press the battery into the sockets until seated. This does not take much pressure. Do not twist or turn the battery as it is installed, as damage to the battery pins or Tracer sockets could result.
14. Place the battery cover squarely over the Tracer body threads. Begin to screw the cover in a clockwise direction. Be careful to not cross thread the cover on the Tracer body threads. The cover should screw on smoothly and easily until the O-ring becomes engaged.

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15. Grasp the Tracer in one hand, clamping the base (probe end) firmly. Then twist the battery cover clockwise until the O-ring seems to disappear.

Never tighten the battery cover more than finger tight. Never use anything to tighten the Tracer Battery Cover except the Tracer Gripper. Over tightening can cause damage to the Tracer cover threads resulting in possible leakage which may damage your Tracer. The design of the Tracer seal is not dependent on high torque to provide an effective seal.

16. With a clean, dry cloth, wipe away any excess Silicone Vacuum Grease that may have been pressed out during closure. Silicone can become extremely slippery in combination with water and could cause the Tracer to slip and be damaged.

The FRB battery installation is now complete. The reassembly procedure, if followed completely, will seal the battery compartment, maintaining the waterproof and pressure-tight seal, as well as the intrinsically safe rating.

Following reassembly of the FRB Tracers, always perform the Test Tracer procedure. This will assure that the battery is functioning properly, the electronics are reset correctly, and the Tracer is initialized.

FRB Battery Conditioning

FRB Battery conditioning is a simple, straightforward procedure. We recommend that conditioning of DataTrace® Batteries take place at a dry, well-lit workstation, just prior to installation in the Tracer. The best place for this activity would be close to the location that Tracers are stored and programmed, Tracer batteries are replaced, and Tracers are assembled and disassembled.

Each set of DataTrace® Modified Battery Clip Connectors (124715-500) can prepare one battery at a time for installation into a Tracer. It is best to have as many Battery Clip Connectors available for the conditioning process as the number of batteries needed for replacement.

FRB Batteries should be installed into Tracers within eight (8) hours of the conditioning procedure. Prepare only enough batteries for the current session of battery replacements.

Remember that replacement of the battery does not automatically recalibrate the Tracer. Normal calibration procedures should be instituted to have each Tracer factory calibrated at least once each year or in conformance with in-house operating procedures.

NOTE:

The batteries used in the DataTrace® equipment are specially designed for this application. USE ONLY BATTERIES SUPPLIED BY DataTrace®. Using any other lithium battery will void the DataTrace® equipment warranty and could damage DataTrace® equipment.

We recommend that batteries are not conditioned at the same time Tracers are disassembled and reassembled. It is very easy to confuse old batteries with new ones and a depleted battery might be reinstalled into the Tracer by mistake.

1. Clear an area to accommodate the DataTrace® Batteries to be conditioned. Do not take any more batteries from their container than are necessary.

Do not allow the battery pins of one battery to contact those of another. This will cause a short which could damage the battery.

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2. Connect the Battery Clip Connectors to the battery terminals. It makes no difference which connector is attached to which of the indicated terminals.
3. The normal conditioning process takes approximately 5 minutes. Allow the battery to lie undisturbed during this period.
4. Remove the Battery Clip Connectors from each battery and allow the battery to "sit" for approximately one (1) minute before installation into a Tracer.

The batteries are now ready for installation into Tracers.

8. System Access

The DataTrace[®] System security is designed for three levels of users:

- **System Administrator** – Responsible for assignment and maintenance of user accounts and defines the DataTrace[®] system configuration.
- **Data and Utilities** – Programs Tracers and reads collected data from process studies, prints data and graphical reports, archives and restores data files, and exports data to external programs.
- **Data Only** – Programs Tracers and reads collected data from process studies, and prints data and graphical reports.

8.1. Establishing Security Levels

DataTrace[®] for Windows (DTW) can be installed with security capabilities that include password protection and data encryption. When enabled, access to various program functions can be strictly controlled. In addition, the program can enable "Electronic Signature" capabilities for compliance with USFDA's 21 CFR Part 11.

DO NOT USE A SECURITY LEVEL THAT IS NOT REQUIRED BY GOVERNMENT REGULATION OR CORPORATE REQUIREMENTS!

The level of password protection is determined during program installation and can not be modified after the installation is complete. There are three levels of security: "None", "Simple", and "Complete".

Note that an "Audit Trail" is created in all levels of security in the DTW program. The System Auditing function generates and maintains an audit trail for certain system events and user activities and stores them in a secure, encrypted table, and includes all events since the DTW program was installed. This table includes: User ID, a date/time stamp, and an action description. The Audit Trail table can be reviewed and/or printed whenever necessary.

None allows the user or users to access all functions of the program without restriction. It bypasses most of the cryptographic features of the program. DataTrace[®] for Windows provides a sophisticated verification of data integrity (SHA-1 algorithm) each and every time you collect and retrieve data. This level is adequate and appropriate for most users of the DataTrace system.

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Simple, in addition to the SHA-1 algorithm, requires that the user login in order to access the program. Each user is then assigned one of three possible authorization levels: "Data Only", "Data and Utilities", or "Administrator". These authorization levels allow access only to those function levels of the program that the user has been approved for. This security level does not implement data signing or auditing necessary to meet USFDA's 21 CFR Part 11.

Complete complies with USFDA's 21 CFR Part 11 and, in addition to the password protection provided with Simple Security, it provides for "Electronic Signatures".

For the two levels of enhanced security available for DTW: "Simple" and "Complete", the System Administrator (Administrator) should make the initial installation of the DTW program. The Administrator assigns passwords and authorization levels and is responsible for system security.

The following provides an overview of the procedures for enabling the secure levels of program operation.

1. During installation the user selects the level of security that the DataTrace[®] for Windows will function under. If "Simple" or "Complete" security is to be enabled, the individual that is assigned the Administrator role should be involved in the installation of the DTW program.
2. The first time DTW is started following installation with an enhanced security level designated, the Login screen appears.
3. Enter "admin" as the Login and "admin" as the Password. This is only valid the first time the program is used following installation, the Password will be changed later.
4. After "admin", "admin" is entered, a dialog box will appear requiring a new Password. Change the Password as instructed on the dialog box: with a minimum of 8 characters and at least one of them must be numeric, no spaces.

There will be a delay while the new Password is recorded, encrypted, stored, and registered.

This is the only Password that will work at the Administrator level. This is important because the Administrator is the only one that has access to the SETUP tab and assigns the authorization levels for other users.

5. The SETUP tab, in enhanced security modes includes all of the program configuration functions plus the USERS Tab. The USERS Tab allows the Administrator to establish new users. This function is only accessible by the Administrator.

The Administrator adds a user by clicking the Add User button. A dialog box appears asking for a user Login, the new user's full name, and authorized security level.

Click the Save button and the new user is added to the Users List. The new user is active and has access to his/her authorized levels when there is a check mark in the "Active" check box of their User data.

A user can not be removed from the Users List, only deactivated. A user is deactivated by removing the check mark from the Active check box.

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6. The first time a new user tries to enter into the program, they will be asked for the login information that was created by the Administrator. On the first time, and only on the first time, the new user enters the login entry for both the Login and Password. A dialog box will appear and require that the new user change to a new Password. Change the Password as instructed on the dialog box: with a minimum of 8 characters and at least one of them must be numeric, no spaces.
7. A regular user has only two options for authorization levels: "Data Only" or "Data and Utilities". No one has access to the Setup options except the Administrator.

While the above discussion defines the Password security that is enabled for both "Simple" and "Complete" security in DataTrace[®] for Windows, it does not address the additional capabilities required for "Complete" security. Specifically, this includes "Signing" capabilities required by the USFDA 21 CFR Part 11, commonly referred to as "Electronic Signatures". The following functions occur only in "Complete" security mode.

8. Data Signing in DataTrace[®] for Windows requires Tracer reads to be digitally "signed" by the user. When a Read is attempted, the user is prompted for his/her User ID and Password. The program then locates and verifies the user record in precisely the same manner as a login, then further verifies that the login information matches the user that is currently logged into the system. If successful, the user's private "signing key" is affixed to the profile along with the User ID.

"Signing Keys" are electronic pairs of encrypted codes that uniquely define that a user is who they say they are. These keys are a matched pair: one "public" and the other "private". By comparing and verifying the user's "private" key, the DTW program validates the target profile. Upon retrieval, the profile exhibits the user's "public" key on the profile.

9. Procedures

This section describes the operation and use of the DataTrace[®] system, including:

- DataTrace[®] system connection
- Installing DataTrace[®] for Windows software
- Programming Tracers for a process study
- Reading collected data
- Analyzing data and generating reports
- Verifying Tracer calibrations
- Calibrating Tracers
- Accessing the audit trail

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9.1. System Connection

Connections for the DataTrace[®] System are very simple. The following details the procedures to follow:

- Clear an area next to the computer as a work area where access to the Serial port (usually located on the rear of the computer) is available. Note that if a USB/Serial Adaptor is being used, it must be installed before the DTW software is installed on the computer.
- Arrange the PC Interface System components for easy access and reference. These components include those items described in section 6 of this document.
- Position the Interface Cable to make connection with the computer's serial port. Carefully align the mating pins and holes, and then press together. This will be a snug fit. Do not force these units together as the small pins may be damaged.
- Tighten the screws on the "ears" of the connectors to both the computer's serial port and the PC Interface. This will prevent accidentally dislodging the cable and breaking communications between the computer and DataTrace PC Interface System.
- Place the Interface Module in a convenient position adjacent to the computer.

9.2. Installing DataTrace[®] for Windows Software

DataTrace[®] for Windows includes an automatic installation program that will start the installation when the CD is inserted into the CD-ROM drive. The DTW installation program works with all Windows operating systems since Windows 95, including Windows NT versions. The following procedure describes the installation of the DataTrace[®] for Windows software.

1. Insert the DataTrace for Windows CD-ROM into your computer's CD-ROM drive. The installation program starts and the "DataTrace for Windows Installation" window is displayed with the following options: "Install DataTrace for Windows", "What's new in DTW", "DTW Password Procedure", "DataTrace Operator Manual (Acrobat PDF)", "Install Adobe Acrobat Reader", and "Exit".
2. Click "Install DataTrace for Windows".
3. The installation program will start and a "Preparing to install..." status box will be displayed. After a slight delay, the "Welcome to the DataTrace for Windows Installation Wizard." screen is displayed. Click Next.
4. The "Security Information" screen appears discussing security systems for DTW. **Read this procedure if you are considering using any Password Protection or Enhanced Security!** Click Next.
5. The "Security Selection" screen appears with three options: "None", "Simple", and "Complete". The program requests you define the level of security that you wish the program to operate under. Select "None" unless you are required to define a higher level of security, then click Next.

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6. The "Installation Type." screen is displayed next. These options allow the DTW program to be loaded on a network where the Network Workstation Installation defines remote workstations. The "Standard Installation" is used to define either the network "server" copy or an individual, stand-alone installation of DTW. Normal installations would use the "Standard Installation". Click Next.
7. Choose the "Destination Folder." from the next screen. The default is C:\Program Files\DataTrace. Normally accept this default. Click Next.
8. The "Ready to Install DataTrace for Windows." screen is displayed. At this point, the Installation program has completed all of its initial procedures. It is now ready to automatically complete the installation. When you press Next, the "Updating System." screen is displayed with bars reflecting the progress of the installation.
9. The final installation screen, "DataTrace for Windows has been successfully installed." appears after the installation is complete. Press Finish to return to the original DTW Install screen. Click "Exit" to exit the DTW Installation screen. The display returns to your Desktop where a shortcut is installed for your DTW program.
10. Double click the DataTrace[®] for Windows icon, which will start your DTW program.

The software installation is complete.

8.3. Operating the DTW program

The computer is the input device to program and retrieve data from the target process via the DataTrace System. The DataTrace[®] System, software and hardware, provides the means to directly interface with the production process.

Start the DataTrace[®] program by clicking on the DataTrace[®] for Windows shortcut icon. The program loads and presents you with the DataTrace Control Panel.

The DataTrace Control Panel is the first screen that appears when DataTrace[®] for Windows starts.

There are four "Tabs" across the top of the Control Panel. Everything done in the DataTrace[®] for Windows program is done from one of these tabs.

The **MAIN** Tab provides access to the most frequently used functions in the program: Programming and Reading Tracers and Analyzing collected data. The MAIN Tab is active when the DataTrace[®] for Windows program starts.

UTILITIES tab provides access to infrequently used file handling and "housekeeping" functions. These include Importing old DataTrace[®] for DOS files, Exporting files into spreadsheets, databases, etc., Archiving or Deleting old or no longer needed profiles, and refreshing the database index. These functions will only be accessed periodically.

The **REPORTS** Tab accesses special reports such as which programs were loaded into which Tracers and listings of Tracer profiles stored in DTW.

The **SETUP** Tab accesses default settings and configuration functions, as well as some special calculations, for the DataTrace[®] for Windows program. Once established, these settings may never need to be visited again.

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Help is available by pressing <F1>. The DataTrace® for Windows Help program is context sensitive and utilizes Hypertext functionality. As an additional aid to the user, the Operator Manual is stored in the DataTrace directory during program installation. The Operator Manual is also accessible from the CD.

8.4. Programming Tracers for Study

To program a Tracer or group of Tracers, click on the Program Tracer button under the MAIN Tab. The Program Tracer screen will appear displaying all of the settings necessary to program a Tracer, along with the Current System Time.

The Current System Time is displayed on the top of the page. Verify that the system time is correct. If the time is not correct, set it by double clicking on the clock displayed on the Task Bar.

Insert a Tracer into the PC Interface Module.

To edit the program that will be loaded into the Tracer(s):

1. The first text box assigns the identification number or code known as a "Run ID". The code can identify a specific batch, run, or shipment of product. The default entry is the "Auto-Number Prefix" and "Initial Value". If programming multiple Tracers, the Auto-Number function programs a sequential number for each Tracer. If another value should be entered in the Run ID (up to a maximum of eight characters), enter it in the text box. Press Enter. The Auto-Number can be defined by clicking the Auto-Number button.
2. Change either the start date or time by typing over the current entry displayed in the Start Time text box.

The Start Time is delayed from the Current System Time based on the last programming session's start delay.

3. The Sample Interval specifies the time interval between samples. The twenty second interval is the factory default. To change the interval, click on the hour, minute, and/or second values until the appropriate values are displayed
4. The table above the buttons displays the maximum duration that the Tracer can collect data based on the Sample Interval selected and the memory capacity of the Tracer. This is displayed in the second column. The third column shows the time of the last point collected.
5. Press the Program button. After a slight pause, a status window appears on the screen stating that the Tracer has been programmed. Press OK to remove the status window.

Remove the Tracer from the Interface Module.

6. To program another Tracer with the same program, put the Tracer in the Interface Module and press the Program button again.

A group of Tracers can be programmed with the instructions contained in the original program. However, in that case, retain the Auto-Numbering default option for the Run ID to sequentially number each Tracer.

7. Click on the Close button to return to the MAIN Tab.

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A permanent record of the Tracer program can be printed indicating the specific program installed and a listing of the Tracers it was loaded into. This listing can be printed when the program session is completed or later from the Reports|Programming Report function.

8.5. Reading Collected Data

To read the process data collected by a Tracer, insert the Tracer in the PC Interface Module, and then click the Read Tracer button to activate the data retrieval process.

All Tracer profiles are saved automatically when a Tracer is read. This ensures data security and integrity. In addition, each profile is saved with a security code that alerts the user if the file is different than when it was originally collected. This "Data Validation" status appears whenever the profile is retrieved or printed.

After the data transfer is complete, the Profile Analysis window appears showing the profile retrieved from the current Tracer in one of three formats: Summary Data, Profile Data, or Graph. These options can be selected at any time, however the selection made during the last Read session will be the default.

1. A summary of the data collected can be viewed by clicking on the Summary Data tab. A summary table for the Tracer appears along with the program used to collect the data. Below the summary table information is a "Comments" text box where up to 80 characters of notes can be entered which are saved with the profile. The comments are displayed whenever the file is retrieved.
2. A complete data list can be displayed by clicking the Profile Data tab. The first column (#) shows the sequence number of the reading, while the second (Sample Time) shows the date and time the samples were taken. The third and subsequent columns show the recorded value and any calculated values that were specified. The units are defined in the column heading above the data and correspond to the engineering units selected in SETUP. The number of decimal places displayed for the collected data are also based on selections made in SETUP. To scroll through the subsequent readings, use the scroll bar.
3. A graph of the collected Tracer data is displayed by clicking on the Graph tab.

A Tracer can be read as many times as desired until it is reprogrammed. However, the data will not be saved again unless the original profile was removed. Also, no additional data is collected by a Tracer after it has been read unless it is reprogrammed.

8.6. Analyzing Data and Generating Reports

VIEWING A DATA REPORT

Reports can be created in both tabular and graphical formats under the Reports tab by clicking on the Graph and Data Reports button. The Data Set tab allows the selection of the profiles to be included in the report.

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8.6.1. Print Data Reports

To obtain a printed report of a Tracer profile, click on the Print Data button and the Create Data Grouping screen appears. This option is used to enter "Lab Notebook" information for a study and to define various phases or profile segments during a study. It is not necessary to complete any of these items to generate a data report. These items are here for user convenience. The default is a single phase that includes all of the collected data without any "Lab Notebook" entries.

1. Enter any appropriate information to complete the Basic Information data screen. This information will appear as the first page of the data report. The "Comments" section can include the detailed description of the study or notes that should be documented.
2. The Profile Phases tab allows study segments to be defined, if necessary. The phases allow the entry of time-based phase or segment periods related to a report or study. The phases have summaries associated with each phase that will be printed in the report. The phases do not need to be contiguous, but can not overlap. It is not necessary to define any phases to obtain a data print out.

A new screen appears requesting a choice between two print options: to do a printout or to preview the printout. Printouts can be made from either option. After the normal Printer screen appears, the data report will be printed.

The printout includes all of the Tracer data displayed on the screen along with the complete data set, plus some additional information. At the top of the first page is the company name as entered in the Setup section. The profile printout lists the Tracer header information just below the company name. The data detail is listed sequentially in columns for all selected Tracers for as many pages as necessary. The footer of each page includes the date printed, a space for the preparer's name, and page information. On the last page of the data report, summary information is printed. If multiple Tracer profiles are printed Minimum, Maximum, and Average values are displayed for each collected sample interval.

If phases were defined summary information will appear for each phase.

The context is returned to the Data Set Tab following the printing operation.

8.6.2. Graph Collected Data

Tracer data graphs are generated in two locations in the DataTrace[®] program. The first is immediately after the Tracer has been read in the Profile Analysis section. The second is by selecting the Display Graph button under Graph and Data Reports. The complete graphing capability is available from the Graph Options tab. The graph can be displayed at any time after the target profiles are selected under the Data Set tab.

1. Click on the Graph Options tab. A set of tabs appear with the TEMPLATE Tab active. In addition, STYLE and PLOT LINES tabs appear.
2. The TEMPLATE screen accesses the various graph formats; one is a factory default, while others are user defined. As many graph templates as necessary can be maintained.

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3. At the top of the TEMPLATE Tab is a drop down text box labeled "Graph Template Name". When clicked a list of all available graph formats are displayed. The "Standard Graph" is the default template.

The default template can not be modified directly, the editing options are disabled. To make modifications a copy of the template must be created. Click on the Copy Template button. This creates a duplicate of the original template.

4. Click on the Edit Name button, and then highlight the current name. Type a new name in the text box, then press ENTER.
5. The STYLE Tab offers graph style or type options. These options include specialized graphs for displaying lethality and deviations from an average profile or a selected (Master) profile. It also defines the legend special data to be displayed e.g., a calculated average profile of the included profiles. The left and right Y axis can be defined for special graph displays. Up to two parameters can be displayed on each axis.
6. The PLOT LINES Tab presents options for special profile line styles, including defining the line styles appropriate for color and non-color printing. Axis formats and set lines can be defined where special Y axis based notations e.g., minimum or maximum values important to the process are displayed.
7. Click on the Display Graph button. A graph is displayed using the data collected earlier and the format defined.
8. Editing of each of the graph elements is accessible by a right click on the target element. An edit menu will appear with various options depending on the nature of the target element. Modify anything that is displayed in these windows and when window is closed, the changes appear immediately on the displayed graph.
9. To print the graph, click on File|Print. The colors displayed on the computer screen will only appear on the printed version if a color printer is used; if no color printer is connected, the print will appear in shades of gray. The ability to differentiate shades of gray may be limited by the print quality and printer resolution.

At the bottom of the printed graph summary data of the profile displayed appears. The same summary information will appear for each profile displayed on your graph.

10. Select the File|Exit menu option to exit the graph module. The format and edit structure is saved in the template automatically, except for those elements that are specific to individual profiles. This template can be used in the future with other groups of Tracer profiles.

8.6.3. Export Collected Data to Spreadsheet

This procedure describes a method of directly exporting collected profile data to an external spreadsheet program. There are six export formats available through the DTW program, two of which are for spreadsheets.

It is important to recognize that by exporting profiles outside the DataTrace® for Windows program, the exported records are no longer secure and it is possible to modify data without being noted in an audit trail. While the original data is retained and unaltered in the DTW system, it is not possible to return the exported copy of data to the DTW program.

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1. Select the export format (Excel).
2. Click the Select Profile button to display a listing of all profiles stored in DTW. From the listing select one or more of the profiles. Click OK.
3. Enter the destination path and file name. Use the Browse function to define the path. The DTW program offers a default name "EXPORT". This name should be changed to avoid overwriting previous files of the same name. Name the file as appropriate, but do not edit the filename extension. Press Enter.
4. Click the Export button. A message warning that the exported file will no longer be secure will be displayed. Click OK. When the Export Complete dialog box appears an Excel spreadsheet has been created. Click OK.
5. The spreadsheet will list all of the selected profiles in columns with the first columns listing date/time. The data appears in columns with the column heading of Tracer serial numbers.

8.7. Verifying Calibration

8.7.1. Temperature Tracer

This procedure describes a method for verifying the temperature measurement accuracy of Tracers. This procedure can be performed on a Tracer any time accuracy needs to be verified.

1. Tracers are normally tested at several temperature points. We recommend that temperature points are selected which are critical in reference to the target process. For example, using Tracers in a sterilization process would suggest using 121°C for a verification point.

The temperature sensor in Tracer is a precision NTC thermistor or a PT2000 RTD. These particular sensors were selected based on their close tolerance and good, long-term stability. DataTrace[®] Tracers are warranted to remain within accuracy specifications for one year from date of purchase.

2. The test is performed by immersing the Tracer's sensing element in an environment that provides a uniform, stable temperature, and immersing a temperature reference standard (reference) into the same environment for comparing the measurements of the reference against the Tracer's measurements.
 - A. Constant temperature liquid circulating baths are recommended to provide the temperature environment up to 150°C (FRB Tracers) or 140°C (MPIII Tracers) with minimum specifications of 0.005°C uniformity and 0.005°C stability. For temperatures above that, an oven with an isothermal block should be used. The isothermal block provides thermal coupling between the Tracer(s) and the reference, and should have uniformity and stability better than 0.050°C.
 - Dow 200 silicone fluid with a viscosity of 5 centistokes is recommended as the medium in the constant temperature bath for temperatures below 10°C.
 - Distilled water can be used as the medium in the constant temperature bath for temperatures from 10°C to 80°C.

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- Dow 200 silicone fluid with a viscosity of 20 centistokes is recommended as the medium in constant temperature baths for temperatures from 80°C to 150°C. Silicone fluid should not be heated above 150°C for testing Tracers.

- B. The standard used should be accurate to 0.025°C or better and traceable to N.I.S.T.

The constant temperature baths should be installed, operated and maintained in accordance with the bath manufacturer's instructions and with the Material Safety Data Sheets (MSDS) s of the manufacturer of the silicone fluid.

The oven shall be installed, operated and maintained in accordance with the manufacturer's instructions.

- Set up the bath or baths and allow them to stabilize at target temperature for 15 to 30 minutes.
- Program the Tracers to be tested for 30 second intervals, starting approximately 15 minutes before they will be immersed into the baths or positioned in the oven.
- Synchronize your computer clock with your time standard or wrist watch.
- For LoTemp, Standard Temp, and MPIII Tracers to be tested in baths:

- C. When placing Tracers into the bath, position their probe tips in such a way that when they are submerged the tips will be at least 1" away from the bottom or sides of the bath, and will be submerged at least 1½" below the fluid level. Tie wraps can be used to help position the probe tips of flex Tracer probes.

Some custom length rigid probes do not fit into the baths. A bath lid should be used that has holes appropriate for inserting the probes into the bath through the lid.

- D. Cover the bath with the lid and insert the reference into the hole in the lid. Slide it in to a level that places its tip near the middle of the bath. For best results try to position the reference probe and the Tracer probes as close to each other as possible without touching. Observe the minimum immersion depth for the reference probe.
- E. After the Tracers have been immersed for 15 minutes and the temperature indicated on the display of the reference probe has stabilized, record the indicated temperature and time.
- F. Repeat steps 1 through 3 for each additional temperature point.
- G. Read Tracer and compare Tracer data to the time and reading from the reference probe.
- H. For High Temp Tracers to be tested in the oven:

CAUTION: TEMPERATURES OVER 140°C WILL DAMAGE THE MPIII TRACER'S ELECTRONICS AND BATTERY. TEMPERATURES OVER 150°C WILL DAMAGE THE FRB TRACER'S ELECTRONICS AND BATTERY. USE A FACTORY RECOMMENDED THERMAL PACK TO PROTECT THE TRACER'S ELECTRONICS AND BATTERY.

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- I. Program the Tracers to be tested for 30 second intervals, starting approximately 15 minutes before they will be placed in the oven or dry well calibrator.
- J. Insert the programmed Tracers into the isothermal block in the oven or into the holes in the dry well calibrator.
- K. Insert the reference probe into the isothermal block in the oven or into the appropriate hole in the dry well calibrator.
- L. Set the oven temperature for 125°C nominal.
- M. Wait for the temperature indicated on the reference's display to stabilize. When it seems to be stable, write down the temperature indicated and wait 10 minutes. If it has not changed by more than 0.1°C in 5 minutes it is stable enough for a reading.
- N. Write down the time and temperature, then set the oven for 205°C nominal and repeat step 5.
- O. Write down the time and temperature, then set the oven for 275°C nominal and repeat step 5.
- P. Write down the time and temperature, and then turn the oven or dry well calibrator off.

CAUTION: BE SURE TO WEAR WELDERS GLOVES WITH GAUNTLETS WHEN HANDLING HOT OBJECTS FROM THE OVEN!

- Q. After the Tracers have cooled enough to handle comfortably, remove them from the oven.
- R. Read the data out of the Tracers with the DT program.
- S. Compare the temperature the Tracers measured with the recorded temperature the reference indicated.

CAUTION: MAKE SURE YOUR PROCEDURE DOES NOT EXCEED THE THERMAL PACKS TIME AND TEMPERATURE LIMITS!

8.7.2. Humidity Tracer

This procedure describes a method for verifying the humidity measurement accuracy of Humidity Tracers. The temperature calibration should be verified with the procedure in section 8.6.1. before the humidity calibration is verified. If a bath is used for temperature verification, a protective cap (124756-002) must replace the normal dust cover on the Humidity Tracer before it is submerged in the bath. This humidity procedure can be performed on a Tracer any time accuracy needs to be verified.

- A. Tracers are normally tested at several humidity values. We recommend that humidity values are selected which are critical in reference to the target process.
- B. The test can be performed by using either a humidity generator or a fixture with certified salt solutions.

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- The humidity generator must have $\pm 1\%$ accuracy or better.
- Salt solutions must be traceable with $\pm 1\%$ accuracy or better.
- C. If a humidity generator is being used, set the humidity chamber to the target humidity per manufacturer's instructions. If salt solutions are being used, install the target salt solution in the fixture per manufacturer's instructions.
- D. Program the Humidity Tracers to be tested for 30 second intervals, starting 15 minutes before they will be inserted into the humidity environment.
- E. Unscrew and remove the sensor dust cover from the Humidity Tracer.
- F. Place the Tracer(s) into the humidity generator or connect the sensor into the humidity fixture per manufacture's instructions. If salt solutions are used, place the Tracer and fixture in an insulated container to stabilize the temperature during the study.
- G. Allow the humidity to stabilize. The length of time depends on whether a humidity chamber or salt solutions are used and the humidity target. Stability could require up to several hours.
- H. Remove the Humidity Tracer from the chamber or fixture and up load the data via DTW.
- I. Compare the value displayed by the Humidity Tracer with the target humidity value from the chamber or the salt solution.
- J. If the humidity value indicated by the Humidity Tracer is outside of an acceptable range, either return the Tracer to the factory for service or perform the calibration procedure described in section 8.7.2.

8.7.3. Pressure Tracer

This procedure describes a method for verifying the pressure measurement accuracy of Pressure Tracers. The temperature calibration should be verified with the procedure in section 8.6.1. before the pressure calibration is verified. This pressure procedure can be performed on a Tracer any time accuracy needs to be verified.

- A. Tracers are normally tested at several pressure values. We recommend that pressure values are selected which are critical in reference to the target process.
- B. Program the Pressure Tracers to be tested for 30 second intervals, starting 15 minutes before they will be connected to the pressure circuit.
- C. The test is performed by connecting the Tracer's sensing element to an environment that provides a uniform, stable pressure, and connecting a pressure reference standard (reference) into the same pressure circuit for comparing the measurements of the reference against the Tracer's measurements.
 - The pressure circuit must provide a stable pressure (or vacuum) source.
 - The pressure reference used should be accurate to 4 times the target accuracy of the Tracer or better and traceable to N.I.S.T.

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- D. Unscrew and remove the sensor cover from the Pressure Tracer. Replace the cover with a Hansen Fitting (124770-500) or Hansen Fitting w/Tube (124770-501).
- E. Connect the Hansen Fitting to a female disconnect on the pressure circuit. If a disconnect is not installed on the pressure circuit, the Hansen Fitting w/Tube can be connected via a ¼ inch compression fitting.
- F. Set the pressurized circuit to the target pressure and allow it to stabilize for several minutes.
- G. Note the time and pressure value indicated on the reference device.
- H. If verification of pressures at various temperatures is required, it is possible to place the Tracer, reference, and pressure circuit in an oven that can maintain a stable elevated temperature.
- I. Remove the Pressure Tracer from the circuit and upload the data via DTW.
- J. Compare the value displayed by the Pressure Tracer with the value noted from the reference at the time noted in step G.
- K. If the pressure value indicated by the Pressure Tracer is outside of an acceptable range, return the Tracer to the factory for service.

8.8. Calibration

The following procedures provide instructions for performing field calibrations on DataTrace[®] equipment. There are two types of calibrations that are possible. The first is for temperature in the Micropack III version temperature-only Tracers, and the second is on all versions of Humidity Tracers.

Both procedures depend on a simple procedure to guide the user through the process. The guideline presents simple instructions to enter information and then automatically generates the new calibration for the target Tracer. The instruction sets for both the temperature-only wizard and the humidity are very similar in order to avoid user confusion.

Normally, if the instructions are followed and the calibration environment is stable and appropriate there is no problem with the successful completion of the calibration procedure. However, if problems are encountered, the last factory calibration can be restored by pressing the "Reset Factory Calibration" button on the Calibration Information screen. The Reset Factory Calibration button only becomes active if the target Tracer has received a field calibration since the last factory calibration.

It is important to note that field calibration will invalidate the factory calibration certification that was originally shipped with the Tracer. The best calibration results will be provided from a factory calibration.

8.8.1. Temperature Tracer

The following instructions perform a temperature sensor recalibration on the DataTrace[®] Micropack III (MPIII) Tracer.

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We recommend that a recalibration be performed on a Tracer **only** when a drift in its temperature accuracy is detected and verified. Furthermore, there are considerations related to the reference environment that must be adhered to. If these requirements can not be met in the field, it is best to return the Tracers to the factory for calibration and certification.

- The minimum calibration dwell time in a **stable** environment is 20 minutes per point. This means that the bath or isothermal block must have attained the target temperature and stay at that temperature for at least 20 minutes for each point for an acceptable calibration to be performed.
- The stability of the reference environment is critical to a good calibration. The field calibration requires 0.05°C environmental stability for the calibration to be completed successfully. The factory calibration stability is 0.003°C.

The DataTrace[®] Temperature Calibration program allows great flexibility with respect to selecting the appropriate calibration points to match the requirements of the application and also accommodate changing needs and capabilities in the future. However, once the procedure is initiated, instructions must be followed explicitly to complete the calibration process successfully.

Once implemented, the program is automatic by following the instructions presented on the screen.

The temperature calibration program is entered from the Program Tracer window under the MAIN Tab of the DataTrace Control Panel. Select Calibration Mode by clicking on that option. Calibration Mode initiates the calibration process that creates, verifies, and installs new calibration coefficients into a temperature Tracer in either a One Point or a Two Point Calibration cycle. The calibration process starts when the Program button is pressed. However, the calibration screens will not appear until the Tracer is retrieved from the reference environment and then Read in the Calibration Utility.

A One or Two Point Calibration optimizes a Tracer to a particular process or application. In most cases it is best to perform a two point field temperature calibration. In a two point calibration plan for the lower target calibration temperature to be 10°C below the lowest process temperature and the higher temperature should be 10°C above the highest process temperature. As a rule of thumb, do not use a two point calibration where the range of interest is less than 75°C. For this small of a range, use a one point calibration where the critical target temperature value is defined to "focus" the calibration on that critical temperature. If a two point calibration with a range less than 20°C is attempted a Range Error will be generated and the calibration will be aborted.

Procedure for a One or Two Point Temperature Calibration

The procedure for a One or Two Point Calibration is almost the same. The primary difference is that for a two point calibration be prepared to expose the target Tracer to two temperature environments during the process, and the Calibration Wizard will request information on two references rather than just one. The procedure is listed below.

1. Select the Calibrate Mode option on the Program Tracer screen. The temperature calibration procedure starts by automatically programming the Tracer with a special program called "CALBRATE". (Note the missing "i" in calibrate.) Press the Program button.

When initiated, a dialog box appears, stating that the calibration program has been loaded into the Tracer and that the Tracer must be placed into the appropriate reference environment. Do this as soon as possible as the Tracer starts taking readings once each minute beginning at the time it was programmed.

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If a two point calibration is being performed, allow sufficient time to transfer the target Tracer between the two reference environments and/or to allow the first bath to stabilize at the second point.

2. Note that a calibration requires at least 20 minutes in a stable environment for each point. It is always best to error on the side of allowing too much time rather than too little.
3. Place the target Tracer into the selected calibration reference environment for the specified amount of time.

Note the reference temperature value(s) used and the time when each target reference temperature is attained and is stable. Write these values down so they are not forgotten.

4. Retrieve the target Tracer from the reference environment after the required minimum stabilization time. Prepare to read the Tracer.
5. Return to the UTILITIES Tab of the DataTrace Control Panel. Place the Tracer in the PC Interface and press Read Tracer. The calibration program will determine that the Tracer is in the midst of performing a temperature calibration.

When the Tracer is read following the calibration procedure listed above (steps #1 thru #5), answer the questions and fill in the blanks as described in the instructions displayed.

6. On the first screen, select the parameter to calibrate and whether a Single Point or a Two Point calibration is needed.
7. Select the Tracer Reading (what the Tracer is actually reading) from those indicated in the drop down box on the left side of the screen. Select the temperature value that is closest to the time that the Reference Value was determined.
8. On the next box, enter a reference value (what the Tracer should be reading), then enter a reference name and/or description. Enter a description in the text box on the left side of the screen. This data is used to document the calibration and will be stored in the Calibration History log.

Items #6, #7, and #8 are repeated for the second point if a Two Point Calibration was selected.

9. On the next screen, a summary of the one or two points is displayed showing for each point the original and corrected values. This information will be placed into the Calibration History report.
10. On the final screen of the calibration, enter any comments in the space provided. Enter the Operator's Name for documentation purposes. Also, to print a Report of Calibration, enable that option at this time.

The Temperature Calibration is complete, press Finish. A "Calibration Complete" screen will appear, press OK.

8.8.2. Humidity Tracer

The following is the procedure for a DataTrace[®] Humidity Tracer sensor recalibration. Note that the procedure does not provide for calibrating temperature or pressure Tracers or the temperature sensor of humidity Tracers, only the humidity sensor.

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We recommend that a recalibration be performed on a Tracer **only** when a drift in humidity accuracy is detected and verified or when a humidity sensor needs to be replaced. Accuracy drift rate and sensor life expectancy are process related.

The DataTrace® Humidity Calibration program provides great flexibility in selecting the appropriate procedure to match the requirements of the application. However, once a procedure is initiated, instructions must be followed explicitly to complete the calibration process successfully. Each procedure has advantages and disadvantages based on cost, time, and complexity.

There are three elements that can help define the appropriate procedure:

- **Sensor Status** (Existing Humidity Sensor, New Humidity Sensor)

Sensor Status is defined by whether an existing humidity sensor is to be calibrated or a new, replacement humidity sensor is to be calibrated.

- **Reference Environment** (Salt Solutions, Humidity Generator)

Reference Environment is defined by the reference standards and/or equipment available to perform the calibration process. A calibration can be no more accurate than the reference environment; use the best available references to obtain the best possible calibration.

- **Calibration Process** (One Point, Two Point, or New Sensor Calibration)

Calibration Process is defined by the application and the level of accuracy the application requires. One and Two Point Calibrations optimize the humidity sensor for use in a particular application, while a New Sensor Calibration is a special calibration to optimize the humidity sensor to the Tracer's hardware.

Decide which Reference Environment and Calibration Procedure is right given the Sensor Status, available equipment, time, and required accuracy. The best possible calibration will require using not only the target humidity of the process but also the target temperature of the process. If it is not possible to calibrate at or near the process temperature, ensure that the temperature remains stable during the entire field calibration.

Once implemented, the program is automatic by following the instructions presented on the screen. For more detailed instructions than those displayed on the screen by the program, refer to the information below.

UNDER NO CIRCUMSTANCES SHOULD A HUMIDITY SENSOR THAT WAS CALIBRATED IN ONE HUMIDITY TRACER BE MOVED TO ANOTHER HUMIDITY TRACER!!

THE HUMIDITY CALIBRATION PROCESS WILL MOST LIKELY FAIL!!

The rH sensor calibration program is entered from the Program Tracer window under the MAIN Tab of the DataTrace Control Panel. Select Calibration Mode by clicking on that option. Calibration Mode initiates the calibration process that creates, verifies, and installs new calibration coefficients into a Humidity Tracer in either a One Point or a Two Point Calibration cycle. The calibration process starts when the Program button is pressed. However, the calibration screens will not appear until the Tracer is retrieved from the reference environment and then Read in the Calibration Utility.

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CALIBRATION OF AN EXISTING HUMIDITY SENSOR:

A One or Two Point Calibration optimizes a Tracer to a particular process or application. A target humidity value (One Point) or a range (Two Point) is defined by the user on which to “focus” the calibration. If the critical humidity range of the process is $\pm 10\%$ rH, a One Point Calibration would be adequate. A wider process range would suggest a Two Point Calibration may be best.

When a One Point Calibration is used, a reference humidity value should be selected very close to the “most important” humidity value in the process. When a Two Point Calibration is used, the reference humidity values should closely bracket the complete process humidity range. Humidity reference values can be obtained from either salt solutions or a humidity generator.

A reference guideline for future calibrations would suggest that if an accuracy drift is detected that is consistently high or consistently low over the range, use a One Point Calibration. Use the Two Point Calibration if an accuracy drift varies over the range.

Note that if a humidity generator is to be used, turn it on, set the appropriate humidity value, and allow it to stabilize before you start the calibration procedure. If your humidity generator allows a temperature to be set, use a temperature close to your process temperature for best accuracy.

Procedure for a One or Two Point Calibration - Existing Sensor

The procedure for a One or Two Point Calibration is almost the same. The primary difference is that for a two point calibration be prepared to expose the target Tracer to two temperature environments during the process, and the Calibration Wizard will request information on two references rather than just one. The procedure is listed below.

1. Select the Calibrate Mode option on the Program Tracer screen. The temperature calibration procedure starts by automatically programming the Tracer with a special program called “CALBRATE”. (Note the missing “i” in calibrate.) Press the Program button.
2. When initiated, a dialog box appears, stating that the calibration program has been loaded into the Tracer and that the Tracer must be placed into the appropriate reference environment. Do this as soon as possible as the Tracer starts taking readings once each minute beginning at the time it was programmed.
3. If a two point calibration is being performed, allow sufficient time to transfer the target Tracer between the two reference environments and/or to allow the first reference environment to stabilize at the second point.
4. Note that a calibration requires at least 170 minutes for a salt solution to equilibrate for each point. For a humidity generator using a manual input option, it is 30 minutes to equilibrate. Remember that these are minimum time periods. Depending on the ambient environment it may take longer to attain stability. It is always best to error on the side of allowing too much time rather than too little.
5. Place the target Tracer into the selected calibration reference environment for the specified amount of time.
6. Note the reference humidity value(s) used and the time when each target reference humidity is attained and is stable. Write these values down so they are not forgotten.

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7. Retrieve the target Tracer from the reference environment after the required minimum stabilization time. Prepare to read the Tracer.
8. Return to the UTILITIES Tab of the DataTrace Control Panel. Place the Tracer in the PC Interface and press Read Tracer. The calibration program will determine that the Tracer is in the midst of performing a humidity calibration.
9. When the Tracer is read following the calibration procedure listed above (steps #1 thru #5), answer the questions and fill in the blanks as described in the instructions displayed.
10. On the first screen, select the parameter to calibrate and whether a Single Point or a Two Point calibration is needed.
11. Select the Tracer Reading (what the Tracer is actually reading) from those indicated in the drop down box on the left side of the screen. Select the humidity value that is closest to the time that the Reference Value was determined.
12. On the next box, enter a reference value (what the Tracer should be reading), then enter a reference name and/or description. Enter a description in the text box on the left side of the screen. This data is used to document the calibration and will be stored in the Calibration History log.
13. Items #10, #11, and #12 are repeated for the second point if a Two Point Calibration was selected.
14. On the next screen, a summary of the one or two points is displayed showing for each point the original and corrected values. This information will be placed into the Calibration History report.
15. On the final screen of the calibration, enter any comments in the space provided. Enter the Operator's Name for documentation purposes. Also, to print a Report of Calibration, enable that option at this time.

This completes the Two Point humidity calibration process. Press Finish. A Calibration Complete! screen will appear, press OK.

REPLACEMENT AND CALIBRATION OF A NEW HUMIDITY SENSOR:

This section provides instructions for the physical replacement of the humidity sensor in a Humidity Tracer. Following the sensor replacement, the sensor may need to be calibrated. Calibration instructions are also included in this section.

DO NOT ALLOW THE HUMIDITY SENSOR TO BE CONTAMINATED BY DIRT, DUST, FINGER OILS, SALTS, OR LIQUIDS AS IT COULD DAMAGE THE SENSOR AND/OR IT'S CALIBRATION.

WE RECOMMEND THAT POWDER-FREE, LATEX SURGICAL GLOVES ARE WORN AFTER THE SENSOR COVER IS REMOVED TO AVOID SENSOR CONTAMINATION.

- The FRB Humidity sensors are shipped with a cover to protect the sensor from mechanical shocks and contamination. Do not remove the cover until instructed to do so. The MPIII sensors do not need a protective cover.

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- Unscrew the Tracer probe cover and gently remove the old humidity sensor. Avoid unnecessary contact with the temperature sensor (green bead) at the base of the humidity sensor.
- On the new FRB humidity sensor, partially remove the sensor cover until the lead connections are visible. Do not completely remove the sensor cover. For MPIII ignore this step.
- Carefully insert the humidity sensor leads into the open sensor sockets from which the old sensor was removed. For MPIII sensor insert the sensor with the writing towards the temperature tube.
- Carefully remove the sensor cover from the FRB sensor.
- Seat the sensor completely with gentle pressure on the top edge. Do not force the sensor as damage may result.
- Reinstall Tracer probe cover.

The humidity sensor replacement is now complete.

When a new humidity sensor is installed, a special calibration is needed to configure and optimize the new sensor to the Tracer's hardware. The reference values for this special calibration should be a wide range, even if the target process does not require a wide range. The reference values used in this calibration process should be less than 45% rH for the low point and greater than 80% rH for the high point. Ideal new sensor calibration values would be 30% rH and 90% rH. Humidity reference values can be obtained from either salt solutions or a humidity generator.

The calibration procedure for a replacement humidity sensor is similar to that of the Two Point Calibration of an existing sensor described above, except for the selection of the 2SR option. The rH Sensor Replacement program utilizes the same calibration procedure discussed above. Please refer to the previous section, "Calibration of an Existing Humidity Sensor".

Again, note that if a humidity generator is to be used, turn it on, set the appropriate humidity value, and allow it to stabilize before you start the calibration procedure. If the humidity generator allows a temperature to be set, use a temperature close to the process temperature for best accuracy.

Repeat the two point humidity procedure indicated above. When step #10 is reached, the only change is to select the 2 SR option. This will create the new calibration for the new sensor.

8.8.3. Pressure Tracer

Field calibration of the Pressure Tracer is currently not available.

8.8.4. Disable Field Calibration

Normally, if the calibration instructions are followed and the calibration environment is stable and appropriate there is no problem with the successful completion of the calibration procedure. However, if problems are encountered, the Tracer's calibration can revert to the last factory calibration.

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Place the Tracer in the PC Interface, then press the "Reset Factory Calibration" button on the Calibration Information screen. The Reset Factory Calibration button only becomes active if the target Tracer has received a field calibration since the last factory calibration.

8.9. DataTrace® Audit Trail

The DataTrace® for Windows program logs an audit trail providing a complete listing of each critical event that affects the data collected by the Tracers, the data integrity of the stored profiles, and the calibration of the Tracers.

8.9.1. Viewing Audit Trail

The DataTrace® for Windows audit trail is accessible through the Report functions. Click on the Audit Trail button and the audit trail screen is displayed indicating each event, the date the event occurred, the user that caused the event to occur, and a description of the event. This log is a complete listing of all significant events that have occurred since the DTW program was installed. No editing of the audit trail is possible by any user, including the System Administrator.

A print of the complete audit trail is available when the audit trail is displayed on the computer screen. Click on the Print button and a print preview of the output is displayed, click to expand the preview image. Click on the printer icon on the Print Preview toolbar and a copy of the complete audit trail is sent to the printer.