Pipette Tracker Pro

Pipette and Volumetric Calibration Software



LABTRONICS INC.

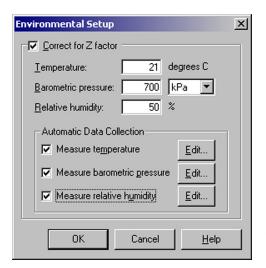
The Instrument Interfacing Experts

Automated Pipette Calibration in a Regulated Environment

Regular performance testing and calibration of liquid handling devices is essential to ensure their precision and accuracy. Potential problems must be identified and corrected before they impact the integrity of laboratory data. Implementing an automated system for scheduling, conducting and documenting performance testing and calibration ensures that these devices are performing according to specifications.

For laboratories working in a regulated environment, Pipette Tracker Pro is the only pipette calibration software that automates gravimetric pipette calibration and record keeping within a framework that meets with regulatory compliance requirements. Pipette Tracker Pro is a secure solution that includes a full security implementation, support for Oracle and SQL Server databases, method validation and method versioning. For regulated laboratories who want to automate pipette performance and calibration testing, Pipette Tracker Pro is the only choice.

Pipette Tracker Pro schedules pipette calibrations, automates data collection during calibration, performs all calculations and corrections and produces all required reports. It is suitable for single and multi-channel pipettes and liquid dispensers of fixed or variable volume, as well as volumetric glassware.



Pipette Tracker Pro brings a new level of automation, organization and documentation to pipette calibration.

- Meets 21 CFR Part 11 compliance requirements
- Meets ISO 8655, DIN 12650, ISO 9000, NCCLS and GLP requirements
- Automatically schedules pipettes for calibration testing
- Automatically collects calibration data from any RS232 balance
- Includes a database of manufacturers calibration specifications for over 700 pipettes
- Maintains a complete calibration history for all pipettes
- Supports Oracle and SQL Server databases
- Includes 4 modes for performing calibrations: Addition, Addition-Tare, Subtraction and Subtraction-Tare
- Corrects for environmental conditions such as temperature, barometric pressure and relative humidity
- Performs all calculations associated with pipette testing

Fully Conforms to International Standards and Procedures

Pipette Tracker meets GLP and ISO 9000 requirements and conforms to the procedures recognized by ISO 8655, DIN Standard 12650 and the National Committee for Clinical Laboratory Standards (NCCLS). Custom protocols, based on a laboratory's internal SOPs, can also be configured and saved.

Environmental Setup. Pipette Tracker Pro automatically corrects for environmental conditions including temperature, barometric pressure and humidity.

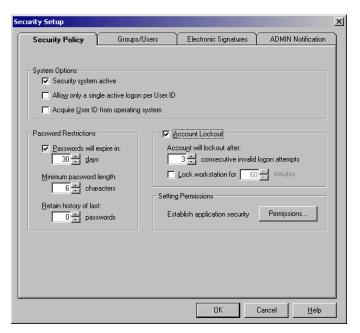
Meet 21 CFR Part 11 Compliance Requirements

Pipette Tracker Pro includes the functionality required to meet with 21 CFR Part 11 compliance requirements:

- User ID and Passwords control access to all areas of the software, assigning appropriate security access levels to each individual user.
- Electronic Signature challenges can require the user to confirm their identity before carrying out critical functions.
- The audit trail function logs all system activity and changes, using date and time stamping. All changes are recorded along with who made the change and why the change was made.
- A workstation can be automatically locked out if left inactive for a specified period of time, preventing undocumented access to an unattended workstation.

Pipette Tracker Pro also includes a validation function that allows the user to validate and assign a version number to methods or test plans. If a valid method or test plan is edited, the valid status will be removed until the edited version has been re-validated. As new versions are created and validated, previous versions are archived for easy reference. Pipette Tracker Pro prevents users from using non-validated methods or test plans.

Pipette Tracker Pro includes the components required to meet with 21 CFR Part 11 compliance requirements.



Security Setup - Security Policy tab. This includes settings that define the basic policy used for security, as well as the security levels for groups/users.

Full Support for Oracle and SQL Server Databases

Pipette Tracker Pro fully supports Oracle and SQL Server databases for maintaining a history of pipette calibration and scheduling calibration testing. Companies using Oracle or SQL Server can implement Pipette Tracker Pro on these platforms ensuring that the application fully meets the requirements and standards of their IT structure.

Improved Organization and Access to Pipette Calibration Data

Information including the serial number, manufacturer, pipette type and pipette location is permanently recorded into the database for each device. For calibration service companies and large enterprises, where large numbers of pipettes need to be monitored, multiple databases can be used to organize and track pipettes by customer, by site, by individual labs, etc. The databases are maintained separately from the main program and are automatically backed up by Pipette Tracker Pro to ensure system integrity.

Pipette Tracker Pro can also track and store information about the pipette tips used for a calibration. If a specific type of tip is specified as part of the Calibration Method, the user will be notified of that at run-time and asked to enter the actual batch number of the tip that is used.

All test results are saved for each pipette providing a full calibration history for each pipette, which can be accessed at any time.

Maintaining a full and secure electronic record of calibration testing results and scheduling eliminates the need for maintenance of paper-based records.



Easy Implementation

Pipette Tracker Pro is an easy-to-install application that is compatible with the most current and popular Windows® Operating Systems.

A key feature of Pipette Tracker Pro is its ability to automatically collect data directly from any RS232-compatible balance, eliminating manual data recording and transcription errors. In order to communicate with the balance, an interface needs to be established between the software and the instrument.

Pipette Tracker Pro includes the Labtronics Instrument Library, a database containing setup information for all of the major balances. The Instrument Library simplifies configuring communication between Pipette Tracker PRo and the balance. Interfacing a balance with Pipette Tracker Pro is as easy as selecting the appropriate device from the listing in the Instrument Library and identifying the COM port that it is connected to.

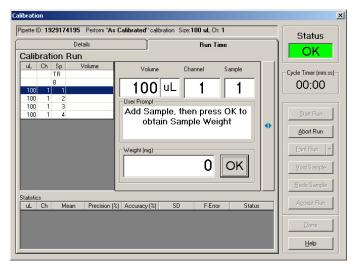
For users who do not have RS232-compatible balances, all of the features of Pipette Tracker Pro are still available by manually entering weighing results. When an RS232 balance does become available, the user can easily switch to the automated balance interface.

Pipette Tracker Pro also includes a manufacturer's database that lists pipette calibration specifications for over 700 pipettes. If a laboratory is using a pipette that is not included in the database, they can easily add it in. These specifications can be imported into a calibration test plan and used to establish testing criteria. This can be a valuable aid in setting up test protocols for different pipettes or groups of pipettes.



Control the Balance from the Software

Pipette Tracker Pro's bi-directional command feature can send any command to the balance that it is capable of receiving and responding to. This feature can be used to prompt the balance to send a weight, tare the balance or even open motorized doors. Commands are sent directly to the balance from Pipette Tracker Pro's Calibration screen



Calibration screen - Run Time tab. The display messages prompt the analyst through every stage of a calibration, showing the required volume and weight received from the balance in large text, to make it easily visible.

Quick Calibration

This feature allows users to calibrate pipettes without scheduling them for future calibrations. All of the pipette information and calibration results are still stored in the database. This is ideal in situations such as at a calibration service provider, where some pipettes may not be calibrated on a regularly scheduled basis.

Cycle Timer

ISO 8655 identifies uneven rhythm and timing as a potential source of error when pipetting. The standard further recommends that, when testing a pipette, the test cycle time be kept to a minimum and be kept as regular as possible.

Pipette Tracker Pro supports the standard by including a Cycle Timer that provides an audible prompt that helps the analyst to pipette at regular intervals. Because it is an audible prompt, the analyst can work accurately and precisely without having to be located right at the computer. The use of the Cycle Timer to promote consistent cycle times increases the accuracy of the calibration process.

Full Automation of All Calculations

Pipette Tracker Pro performs all calculations in accordance with the requirements as defined in ISO 8655.

Environmental variables that are often responsible for adversely affecting gravimetric test results are automatically taken into account. During calibration runs, evaporation, temperature, barometric pressure and relative humidity are immediately factored into mass-to-volume calculations as sample results arrive at the computer from the balance.

Pipette Tracker Pro is unique in that environmental data can be entered into the system three different ways. Where conditions are controlled and consistent, a fixed value can be entered into the software for any of the parameters. This value is then used for calculations with every calibration. Alternatively, the operator can enter a new value for any of the environmental conditions at runtime, ensuring that the calculations reflect the current conditions. Finally, Pipette Tracker Pro can automatically collect the environmental data directly from any measuring devices that are equipped with RS232 ports. This eliminates the need for the operator to enter the values and ensures that accurate environmental data is automatically included in the calculation of pipette performance, each and every time.

After each calibration run, Pipette Tracker Pro automatically calculates all of the statistical results for the pipette using formulae and tables provided in ISO 8655-6. Users have the option to set the statistical range that is used to define the pass or fail criteria of their pipettes. Based on the results of these calculations, pipette results are immediately evaluated and issued a pass or fail tag.

All approved results are recorded in the database, where they provide an on-going history of pipette calibrations.



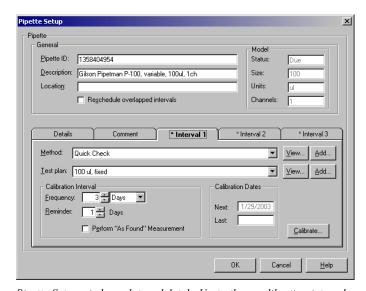
Automated Scheduling

Pipette Tracker Pro automatically schedules calibration testing for all pipettes in the database by automatically checking each pipette record against the current date to determine if testing is due.

If a pipette is due to be tested, it appears on the worklist screen for immediate reference. Pipettes can be set up to appear on the worklist ahead of the testing date to ensure that the pipette is available for testing at the appropriate time

If a pipette needs to be calibrated outside of its regular schedule (e.g. if it is dropped), the user will be prompted as to whether the next calibration should remain as scheduled or if the schedule should be adjusted to reflect the new calibration

Automated scheduling ensures that regular testing takes place without incurring the cost of having to manually monitor pipette testing intervals.



Pipette Setup window - Interval 1 tab. Up to three calibration intervals may be defined for each pipette.

Automated Reporting

Pipette Tracker Pro includes an extensive range of standard reports including worklists, inventory lists, summary and detail calibration reports, device calibration history reports, test plan and method documentation, etc. These reports can be modified to suit specific requirements.

Reports can be saved in a variety of output formats including Word, Excel, PDF, HTML, and TIF. Providing reports in these formats makes Pipette Tracker Pro compatible with virtually any reporting, archiving or document management application.

Reports can be also be created by Pipette Tracker Pro in an ASCII file format and exported to any spreadsheet or SPC application program, for additional reporting and analysis.

Professional Services

The Pipette Tracker Pro software is designed with user setup and ease of use in mind; however, Labtronics understands that not everyone has the time to set up and learn any new software no matter how easy it may be to configure and use.

<u>Contact Labtronics</u> about the services available to help bring your system on-line quickly through our expertise.

Our Guarantee

All Labtronics software products are provided with a 30-day evaluation guarantee. If within 30 days you are not satisfied with our software you may return it to us for a refund. Shipping charges and professional services are non-refundable.

System Requirements

- Windows® 2000 or Windows® XP
- Pentium II 400 or better processor
- RAM: Minimum 128 MB

New in Version 3.2

- Supports Windows® 2000 or Windows® XP
- Optimized design results in improved speed/response time
- Bi-directional communication with all balances
- Support for european numbering formats
- New calibration scheduling option
- New calculation options
- New Reporting Module allows the user to design/ modify reports
- The manufacturers database of pipettes and calibration specifications now includes over 700 pipettes
- Support for Oracle databases
- Support for SQL Server databases
- Enhanced electronic signatures
- Enhanced password protection
- Enhanced audit trail
- Automatically lock the workstation after a defined period of inactivity
- Email notification when a Pipette is due for calibration
- Allows the user to validate and assign a version number to methods or test plans
- Prevents user from running any methods that are nonvalidated
- Archives validated methods for historical reference