FLUKE ®

Calibration

TQSoft and TQAero Thermal Validation Software

Technical Data

For FDA 21 CFR Part 11 and AMS 2750 compliant data collection

The Fluke 2638A Hydra Series III and Fluke Calibration 1586A Super-DAQ are ideal for general purpose and precision temperature data acquisition applications. Thermal validation software from TQSolutions has long supported the Fluke Hydra Series data loggers. TQSoft and TQAero now support the Fluke 2638A and 1586A products for enhanced data collection and reporting required in regulated industries.

Many data acquisition applications require compliance to government and standards agency requirements (for example, 21 CFR Part 11 and AMS 2750). Software from TQSolutions has been designed to enable engineers, technicians, and lab managers to meet the key guidelines for temperature data collection. These software solutions provide a complete qualification, reporting, documentation, and audit trail management system.

TQSoft

- Compliance with United States Food and Drug Administration (FDA) Title 21 CFR Part 11 regulations on electronic records and signatures for incubation, sterilization, freezing, drying and temperature mapping validation applications in pharmaceutical and biomedical industries.

- Developed in accordance with Good Automated Manufacturing Practice (GAMP) from the International Society for Pharmaceutical Engineering (ISPE).

- Compliance with European standards for sterilization, decontamination, and disinfecting (EN554, EN285, EN15883, HTM2010, HTM2030), ISO 15833 requirements for washer-disinfectors, and ISO 17025 competence requirements for testing and calibration laboratories.

- Has been audited by major pharmaceutical companies and its quality documentation has passed FDA audits.

TQAero

- Compliance with National Aerospace and Defense Contractors Accreditation Program (NADCAP) and SAE International AMS 2750 guidelines covering industrial heat treating applications in aerospace and transportation industries.

- Supports heat treatment processes validation by Temperature Uniformity Survey (TUS) and System Accuracy Test (SAT) procedures required by AMS 2750.

Key features

Easy menu system and toolbar

TQSoft and TQAero provide a menu system designed to simplify thermal validation test setup. The left panel guides you step by step. Dropdown arrows on the right list the full range of options. If desired, easily switch to the toolbar for access to all software features.
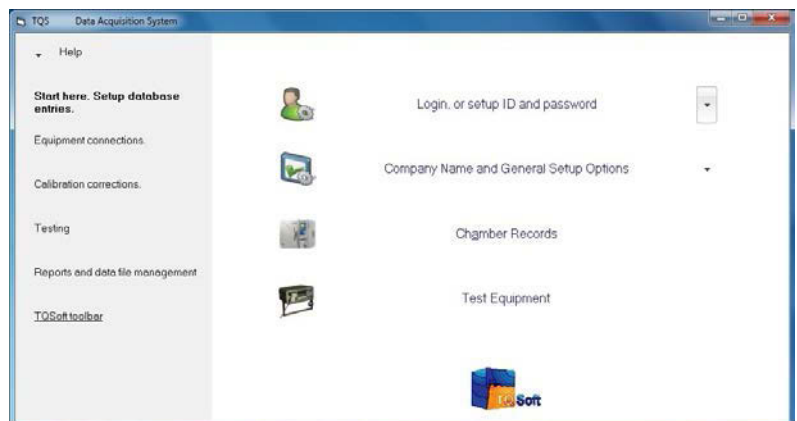

Figure 1. Easy menu system.

Figure 2. Menu toolbar.

Data security and audit trail

TQSoft and TQAero check data files used to produce reports. Any changes made by an unauthorized person will render records unusable. All changes made by an authorized user are audited with full details of the changes made and actions performed.

Test equipment preparation and sensor calibration

Both TQSoft and TQAero guide you through data logger channel configuration and communications setup with a temperature source, thermometer readout, and reference probe. Fluke 2638A and 1586A models are automatically detected as data loggers for easy setup. Prior to a thermal validation test, an automatic or manual sensor calibration can be performed to determine multiple point offsets for each channel to correct for sensor measurement inaccuracy. When the sensors and reference probe are detected to be stable as defined, the software automatically applies all correction offsets, generates, and saves a full and traceable calibration report.

Thermal validation test setup

TQSoft and TQAero allow you to set up and manage a three-dimensional (3D) wire diagram of the chamber space. Drag and drop sensors to their correct position in the 3D space. The completed diagram can be rotated and magnified. There are options for real time display of measurement values and to represent temperature gradients with color shading at each sensor position. After the test is complete, a real time display can be replayed with a time slider showing temperature behavior in the chamber. Completed diagrams can be easily added to reports.

Sample test specifications

Sample test specifications are included to help you quickly become familiar with the software. The test specification contains selection settings for target temperature, channel configuration, all calibration information, and all temperature parameters. When you select a test specification and start a test, all settings are automatically applied by the software, and a report can be automatically generated at the end of the test. Once you are familiar with the software, you can make modifications and create new test specifications to meet your specific needs.
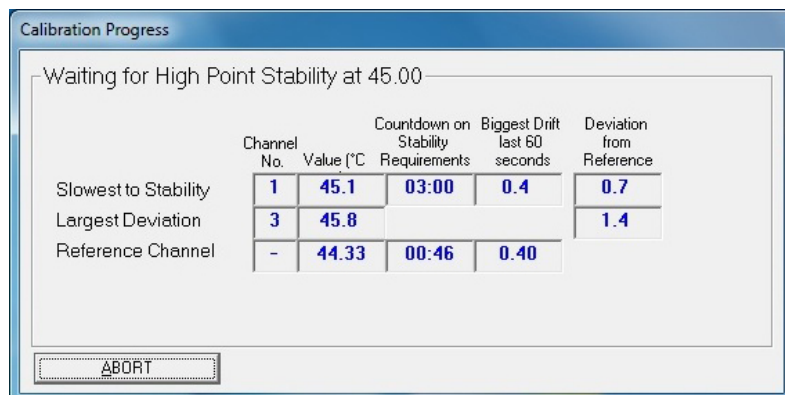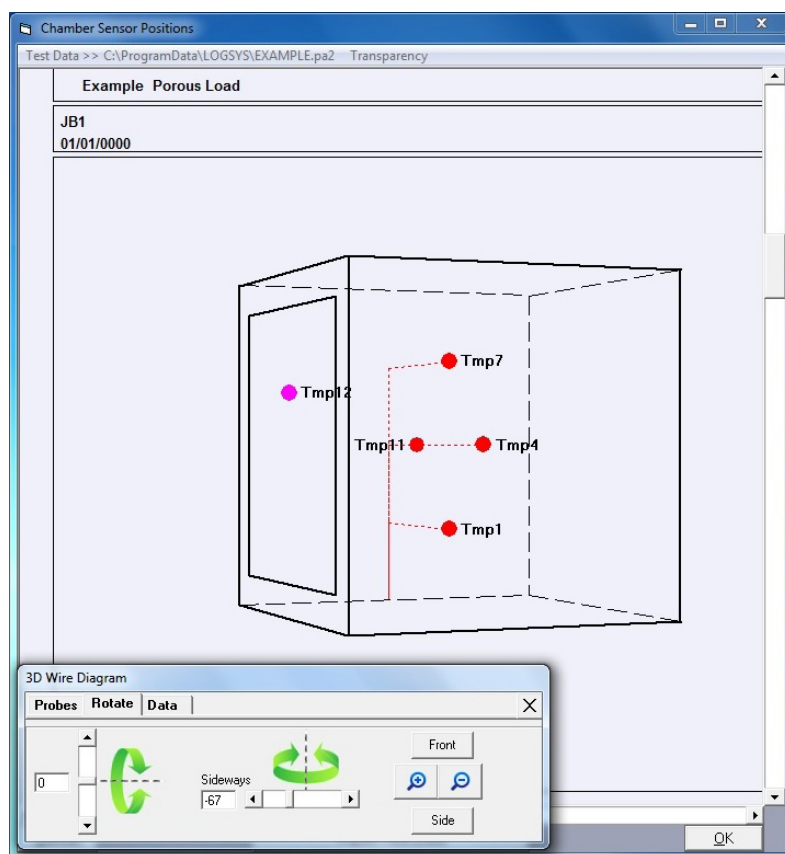

Figure 3. Automatic sensor calibration.

Figure 4. Chamber sensor positions.

Reports

TQSoft and TQAero include a large library of templates for creating reports tailored to the needs of individuals, organizations, processes, and equipment. It's easy to assemble a full report from the report sections. Cover pages, charts, data lists, calibration reports, calibration certificates, etc. can be included. The Report Manager window has been designed to manage and print complete reports.

Fluke Calibration instruments supported

Data acquisition systems

1586A Super–DAQ Precision Temperature Scanner
2638A Hydra Series III Data Acquisition System/ Digital Multimeter
2620A/2625A Hydra Series Data Acquisition Unit/ Data Logger
2635A/C Portable Data Acquisition
2680 Series Data Acquisition Systems
2640A/2645A NetDAQ Data Acquisition Unit

Thermometer readouts

1502A/1504 Tweener
1523/1524 Reference Thermometers

Temperature sources

9142/9143/9144 Field Metrology Wells
9190A Ultra–Cool Field Metrology Well
9170/9171/9172/9173 Metrology Wells
9103/9140/9141 Dry–Well Calibrators
9009 Dual–Block Calibrator
9011 Dual–Well Calibrator
9101 Zero–Point Dry–Well
9007 Portable Lab Dry–Well
6102/7102/7103 Micro–Baths
6330/7320/7340/7380 Compact Baths
6331/7321/7341/7381 Deep–Well Compact Baths
9150 Thermocouple Calibration Furnace

System requirements

One of the following Microsoft operating systems:
Windows XP
Windows 7
Windows 8
Disk space: 250MB

Languages

English

Demonstration

Contact your Fluke representative to arrange a demonstration of the software.

Pricing

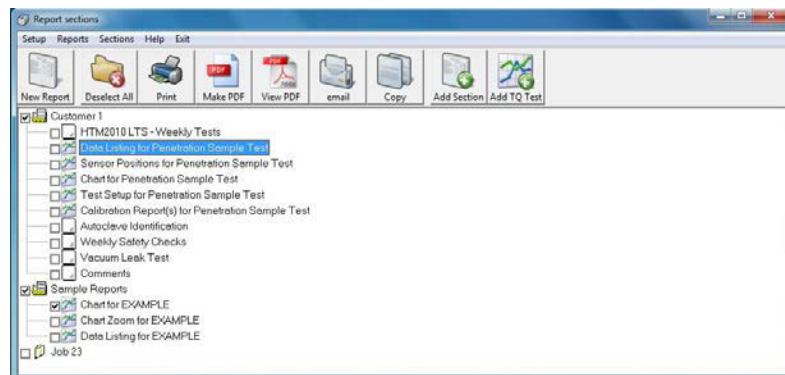Contact your Fluke representative to request a quote.

Figure 5. Reports Manager.

Ordering information

Models	Description

TQSOFT-IQ/OQ   TQSoft Pharma Process Analysis and Validation Software
Data acquisition software with activation key code. Electronic signatures and operator action audit trail. Configurable for use in discrete process validation. Provides FDA 21 CFR part 11 compliant user access controls. Includes IQ/OQ Documentation to help customers test their validation system with their processes. This set of PDF documents on CD provides a test plan to guide customers in TQSoft installation and qualification using their instruments, test specifications, and reporting requirements. Email support and one remote installation and training session is included.

TQAERO   TQAero Furnace Validation Software
Data acquisition software with activation key code. NADCAP compliant user access controls and operator action audit trail. Configurable for use in discrete process validation. TQAero is a configuration of TQSoft providing complete support for AMS2750 requirements. Email support and one remote installation and training session is included.

VAL-BNDR-TQS   Validation Reference Binder
This is a set of TQSolutions documents on CD summarizing TQSoft system acceptance testing to GAMP standards.

Customization and training services

For customers setting up complete validation systems, more extensive support and training is recommended and usually required. A range of customization and training options is available for TQSoft and TQAero. Contact TQSolutions at info@tqsolutions.net to discuss your training requirements.

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Fluke Calibration. *Precision, performance, confidence.*™

Electrical	RF	Temperature	Pressure	Flow	Software