

TQSoft and TQAero

Thermal Validation Software for 1586A Super-DAQ and 2638A Hydra Series III

Product Launch Playbook

TQSoft and TQAero Overview

FLUKE®

**Thermal validation software for the
1586A Super-DAQ and 2638A Hydra Series III
used to meet the data collection and reporting
requirements of regulated industries**



TQSoft: For pharmaceutical / biotechnology companies
Complies with U.S. Food and Drug Administration (FDA)
Title **21 CFR Part 11**, European standards, and ISO
requirements for incubation, sterilization, and freeze drying
applications



**1586A Super-DAQ with
DAQ-STAQ Multiplexer**

TQAero: For heat treatment service / aerospace / auto /
transportation companies
Complies with SAE International **AMS 2750** requirements
for metal heat treating applications



2638A Hydra Series III

TQSoft and TQAero are produced by TQSolutions Ltd.

Who needs it?

Target companies

- Pharmaceutical
- Biotechnology
- Aerospace
- Automotive
- Transportation
- Heat treatment service companies
- Contract validation companies

End-users

- Validation engineers and technicians
- Lab managers

Applications

- **Pharma/Biotech companies:** Thermal studies or validation* of the following equipment -- Autoclaves, Dry heat sterilizers, Ethylene oxide sterilizers, Freeze dryers (lyophilizers), Hot air tunnels, Incubators, Oven dryers, Stability chambers, Steam sterilizers, Sterilization chambers, Washer disinfectors
- **Heat treatment service and Aerospace/Auto/Transportation companies:** Thermal studies or validation* of heat treating furnaces or ovens

** Validation verifies that equipment can meet and maintain its specified temperature*



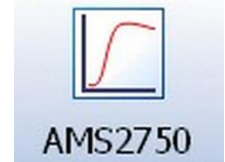
Why do they need it?

Pharmaceutical / biotechnology companies need to comply with various regulations:

- 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
- 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



Heat treatment service and aerospace / auto / transportation companies need to comply with SAE International AMS 2750 guidelines covering industrial heat treating applications



TQSoft and TQAero are designed to meet the enhanced data collection requirements of these industries

TQSoft: Thermal study example

1. Set-up equipment



installed on PC or laptop



Temperature source

- 9190A Field Metrology Well

Reference probe

- 5615 Secondary Reference PRT

Test sensors

- Type T thermocouples



Data acquisition system

- 1586A Super-DAQ with DAQ-STAQ

Other Fluke equipment supported:

Data acquisition system

- 2638A Hydra Series III and previous generations

Thermometer readouts

- 1502A/1504 Tweener
- 1523/1524 Reference Thermometers
- 1560 Black Stack

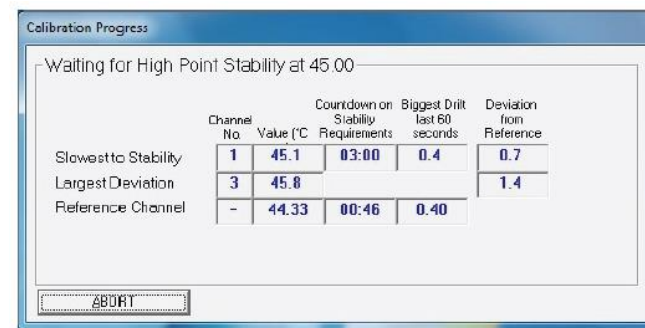
Temperature sources

- 9142/9143/9144 Field Metrology Wells
- 9170/9171/9172/9173 Metrology Wells
- 6102/7102/7103 Micro-Baths
- 6330/7320/7340/7380 Compact Baths
- 6331/7321/7341/7381 Deep-Well Compact Baths
- 9150 Thermocouple Furnace
- Other drywell calibrators

Additional equipment supported from Agilent, Anville, Eurotherm, Kaye, TMI, Yokogawa, Ametek, and Isotech

2. Automatically calibrate sensors

- Enter stability criteria
- TQSoft communicates with temperature source, reference probe, and test sensors
- When reference and sensors are stable as defined, TQSoft automatically applies all correction offsets
- It also generates and archives a full and traceable calibration report

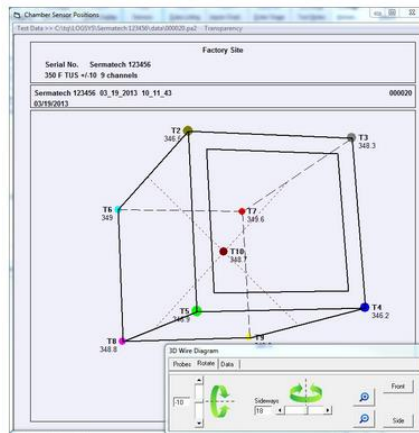


TQSoft: Thermal study example cont.

3. Set-up thermal study for chamber



Stability chamber for pharma/biotech products



- Use TQSoft to manage a 3D wire diagram of the chamber space to be studied
- Position sensors in the correct locations
- Rotate and magnify position diagram. Edit if needed.
- Sample test specifications are included that can be used while learning TQSoft

4. Test and view results



installed on PC or laptop



Data acquisition system
• 1586A Super-DAQ with DAQ-STAQ

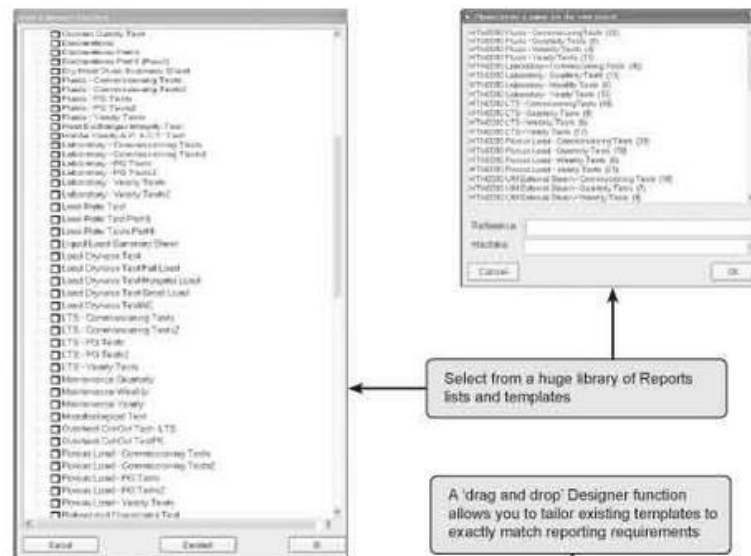


Stability chamber with Test sensors
• Type T thermocouples

- Temperature measurements can be displayed during testing
- Temperature gradients with color shading at sensor positions can be shown
- After testing, replay with a time slider showing temperature behavior in the chamber

TQ Soft: Thermal study example cont.

5. Create report



- TQSoft includes a “Report Manager” for design and printing of reports
- Includes a large library of report templates for all processes
- Reports can include graphics, complex calculations based on acquired test data, lethality formulae, and engineering lookup tables. The calculations and lookup tables can be validated.
- Reports are presentation quality, quickly produced and secure

Instrumentation Check During Exposure Time				
Drain Temperature				
Indicated	Recorded	Measured	Difference	Limit
Hold Indic	Hold Reco	Hold Meas	Hold MFR	Hold MFR
Chamber Pressure				
Indicated	Recorded	Measured	Difference	Limit
Hold Indic	Hold Reco	Hold Meas	Hold MFR	Hold MFR
Timer Accuracy				
Exposure Time				
Indicated	Recorded	Measured	Difference	Limit
Hold Indic	Hold Reco	Hold Meas	Hold MFR	Hold MFR

Cycle Start Time	Cycle Start Time
End of Cycle	Cycle end time
Cycle Time	Total cycle duration
Start Hold Time	Sterilising End of Equi
End Hold Time	Sterilising and time
Hold Time	Sterilising hold time
Start Exposure Time	Sterilising Start of Equi
End Exposure Time	Sterilising and time
Exposure Time	Sterilising plateau time

- **“Are you involved with thermal studies, validation, or chamber mapping?”**
- Pharma/biotech customers: **“Do you need to comply with 21 CFR Part 11 requirements?”** (Tell them about TQSoft. It works with the 1586A and 2638A)
- Pharma/biotech customers: **“Do you need to comply with European and ISO standards for sterilization, decontamination, and disinfecting** (e.g. EN285, EN15883, HTM2010, HTM2030, ISO15833)” (Tell them about TQSoft. It works with the 1586A and 2638A)
- Heat treatment service/aerospace/auto/transportation customers: **“Do you need to comply with AMS 2750 requirements?”** (Tell them about TQAero. It works with the 1586A and 2638A)

- Objection: **“I can meet the 21 CFR Part 11 or AMS 2750 requirements of my industry without buying additional software.”**
- Response: “There is a lot involved in setting-up and carrying out a test process that complies with these regulations. I’d be glad to arrange a demo of TQSoft/TQAero just so you can take a closer look at what it can do for you. You may find it can save you substantial time and money. Plus give you the assurance that you’ve covered all you need to meet regulations (qualification, reporting, documentation, and audit trail).”
- Objection: **“I’ve never heard of TQSolutions (the company who developed TQSoft and TQAero).”**
- Response: “TQSolutions has been serving the thermal validation community since 1994. They specialize in software for acquiring data, analyzing it, and reporting it in a 21 CFR Part 11 or AMS 2750 compliant environment. Their software supports many Fluke data acquisition systems, thermometer readouts, and temperature sources plus popular equipment from other suppliers. I’d be happy to arrange a product demo so you can evaluate what it can do for you.”

- Objection: **“Is Fluke trying to compete with the Kaye Validator?”**
- Response: “No, Kaye is a valuable Fluke business partner. We work closely with Kaye to qualify our products for use with their validation solution. However, some customers want to use the 1586A/2638A data acquisition products in regulated industries to comply with 21 CFR Part 11 or AMS 2750 requirements. We offer TQSoft and TQAero to address these customer requests.”

Non-exclusive products sold by FCAL direct sales people and PCT distributors

Distributor compensation: PCT product level discount

TQSolutions exclusive countries:

- TQSoft and TQAero are already being sold in the following countries by TQSolutions agents:
 - UK, Ireland, Netherlands, Mexico, Egypt, Japan, China, South Korea
- For sales opportunities of 1586A/2638A with TQSoft or TQAero in these exclusive countries:
 - Fluke reps or channel partners should book the 1586A/2638A order
 - Coordinate with the TQSolutions agent to book the software order for TQSoft or TQAero: See contact information for agents on next slide

TQSolutions agents for exclusive countries:

UK and Ireland – Isopharm, Coordinate through Ian Hinchcliffe (FCAL Western Europe RPM)

Netherlands – TT&MS, Andre Handgraff, +31 (0)252 621 080, info@ttms.nl

Mexico – ValCal, Salvador Negrete Centeno, (33) 36 66 03 94, salvador.negrete@valcal.com.mx

Egypt – Egyptian Engineering Systems, Osama Kamel, 00 20 1277 60342, osama@ees9.com

Japan – Measurement Instruments, Kaz Ueyama, 080-6157-3350

China – Intelligent Technology Co., Albert Wang, +86 21 54832726/54832725 , xinbing.wang@pharmeng.net

South Korea – Tessol, Seung-Woo Han, +82-10-7317-5988, swhan@tessol.com

TQSoft and TQAero Models


For FCAL direct sales people (RSMs/RPMs/IS) and distributors:

Model	Description		What's Included
TQSOFT-IQ/OQ	TQSoft Pharma Process Analysis and Validation Software		TQSoft software, manual, IQ/OQ documentation (test plan for guiding customers in TQSoft installation and qualification)
TQAERO	TQAero Furnace Validation Software		TQAero software and manual
VAL-BNDR-TQS	Validation Reference Binder		Documents summarizing TQSoft system acceptance testing to GAMP standards

TQSoft and TQAero Product Launch Page

<http://us.flukecal.com/TQSoft-TQAero-Software-Launch>

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TQSoft / TQAero Thermal Validation Software

Welcome to the launch page for the TQSoft / TQAero Thermal Validation Software for 21 CFR and AMS 2750 regulatory requirements. Comply with key requirements for temperature 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 TQ Solutions 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.

Collateral
[Datasheet »](#)

E-advertising
[1586A HTML email »](#)
[2638A HTML email »](#)
[EMEA HTML email »](#)
[Web banners »](#)
[TQ Solutions Product web page »](#)

Sales tools
[To download these assets visit the TCAL Partner Portal »](#)
Search by the asset number:
Product announcement
Asset #TBD
Sales presentation
Asset #TBD
Customer presentation
Asset #TBD
Catalog copy – Full page
Asset #TBD
Catalog copy – Half page
Asset #TBD
Catalog copy – Quarter page
Asset #TBD

Screen captures
- 156 DPI
[Automatic Sensor Calibration »](#)
[Easy menu system »](#)
[Reports Manager »](#)
[Chamber sensor positions »](#)
[Menu toolbar »](#)

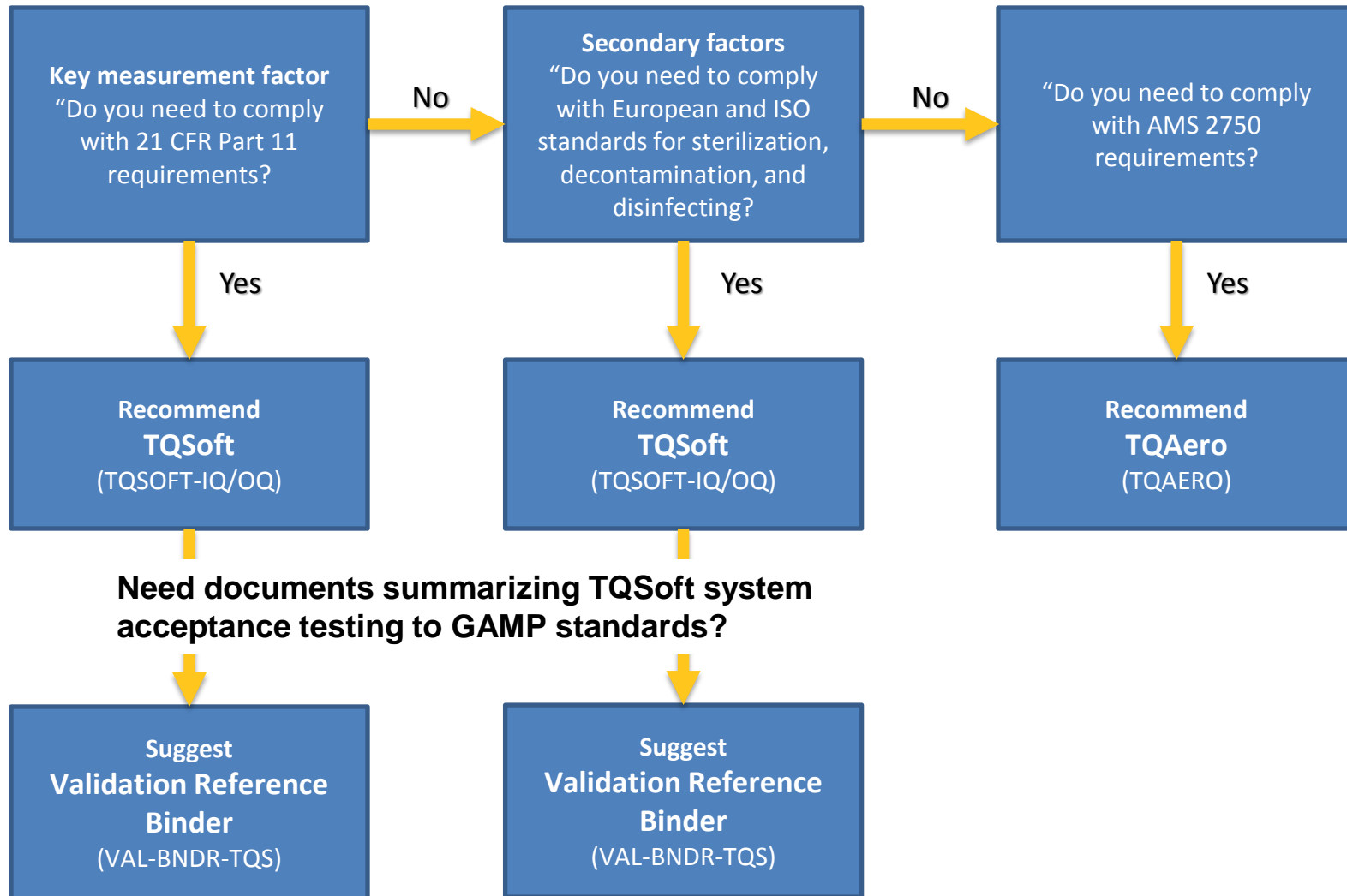
FCAL Launch Pages
[8790B AC Measurement Standard »](#)
[MET/TEMP II Temperature Calibration Software v5.0 »](#)
[Fluke DAQ 6.0 Application Software »](#)
[4322 Automated Pressure Calibration System »](#)
[9118A Thermocouple Calibration Furnace »](#)
[95000 Series RF Reference Sources »](#)
[6003A Three Phase Electrical Power Standard »](#)
[6135A/PMUCAL Phasor Measurement Unit Calibration System »](#)
[1586A Super-DAQ Precision Temperature Scanner »](#)
[2638A Hydra Series III Data Acquisition System »](#)
[3130 Portable Pneumatic Pressure Calibrator »](#)
[2700G Series Reference Pressure Gauges »](#)
[9190A Ultra-Cool Dry-Well Calibrator »](#)
[7526A Precision Process Calibrator »](#)
[TCAL and FCAL Gold Care Plans »](#)
METTEAM »

Demonstration: Customers will contact their Fluke rep to request a demo. Fluke reps contact Richard Bridger at info@tqsolutions.net to schedule a product demonstration. Distributors may purchase a demo copy of TQSoft or TQAero from Fluke at their standard product discount plus an additional 10%.

Support: First consult the Quick Start Guide for general software set-up and usage. Contact electricalsupport@flukecal.com for TQSoft/TQAero support issues with the 2638A. Contact temperaturesupport@flukecal.com for TQSoft/TQAero support issues with the 1586A. The Fluke teams will manage support escalation with TQSolutions as needed.

Training: One remote installation and training session is included with a purchase of TQSoft or TQAero. 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.

Selection guide logic



Knowledge check

Question	Answer
1. TQSoft is for customers in which industries?	Pharmaceutical, Biotechnology
2. TQAero is for customers in which industries?	Aerospace, Automotive, Transportation
3. What United States Food and Drug Administration (FDA) standard does TQSoft help customers comply with?	Title 21 CFR Part 11
4. What key SAE standard does TQ Aero help customers comply with?	AMS 2750
5. Fluke includes the IQ/OQ Documentation (test plan for guiding customers in TQSoft installation and qualification) with which product?	TQSoft
6. Who do you contact to arrange a product demonstration for your customer?	Customers will contact their Fluke rep to request a demo. Fluke reps contact Richard Bridger at info@tqsolutions.net to schedule a product demonstration. Distributors may purchase a demo copy of TQSoft or TQAero from Fluke at their standard product discount plus an additional 10%.
7. Who do customers contact for support?	First consult the Quick Start Guide for general software set-up and usage. Contact electricalsupport@flukecal.com for TQSoft/TQAero support issues with the 2638A. Contact temperaturesupport@flukecal.com for TQSoft/TQAero support issues with the 1586A. The Fluke teams will manage support escalation with TQSolutions as needed.
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