TQSoft and TQAero

Software for the 1586A Super-DAQ or 2638A Hydra Series III used in thermal validation studies to meet the data collection and reporting requirements of regulated industries

1586A Super-DAQ with DAQ-STAQ Multiplexer

TQSoft – For pharmaceutical / biotechnology companies:

- United States Food and Drug Administration (FDA) **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

2638A Hydra Series III

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

21 CFR Part 11

AMS2750

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

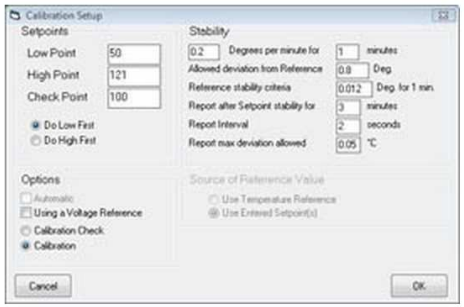
Thermometer readouts
- 1502A/1504 Tweener
- 1523/1524 Reference Thermometers
- 1560 Black Stack

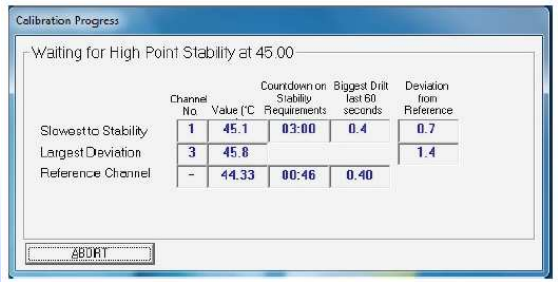
Temperature sources
- 9142/9143/9144 Field Metrology Wells
- 9170/9171/9172/9173 Metrology Wells
- 6102/7102/7103 Micro-Baths
- 6330/7320/7340/7380 Compact Baths
- 6331/7321/7341/7381 Deep-Well Compact Baths
- 9150 Thermocouple Furnace
- Other drywell calibrators

Addional 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

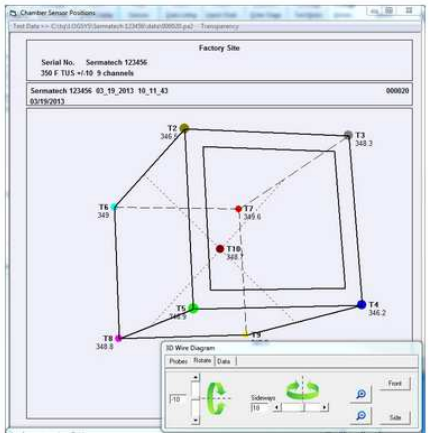




TQSoft: Thermal study example cont.

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

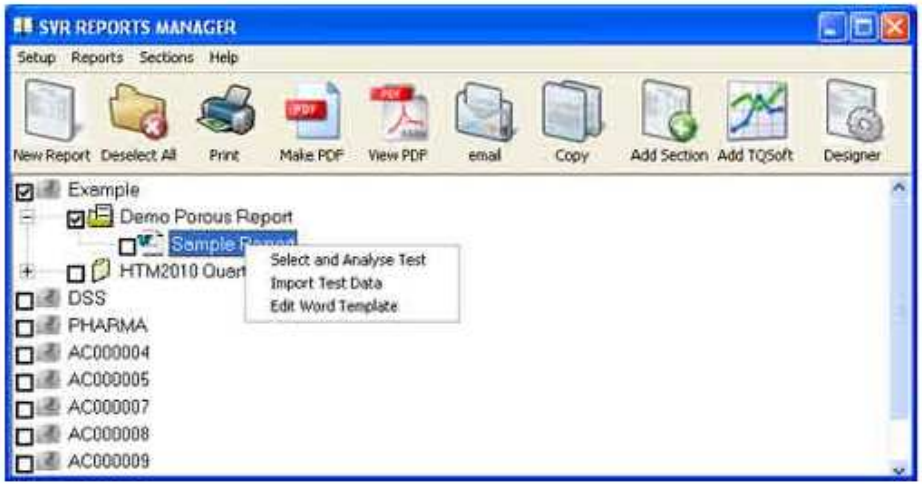
Data acquisition system
- 1586A Super-DAQ with DAQ-STAQ

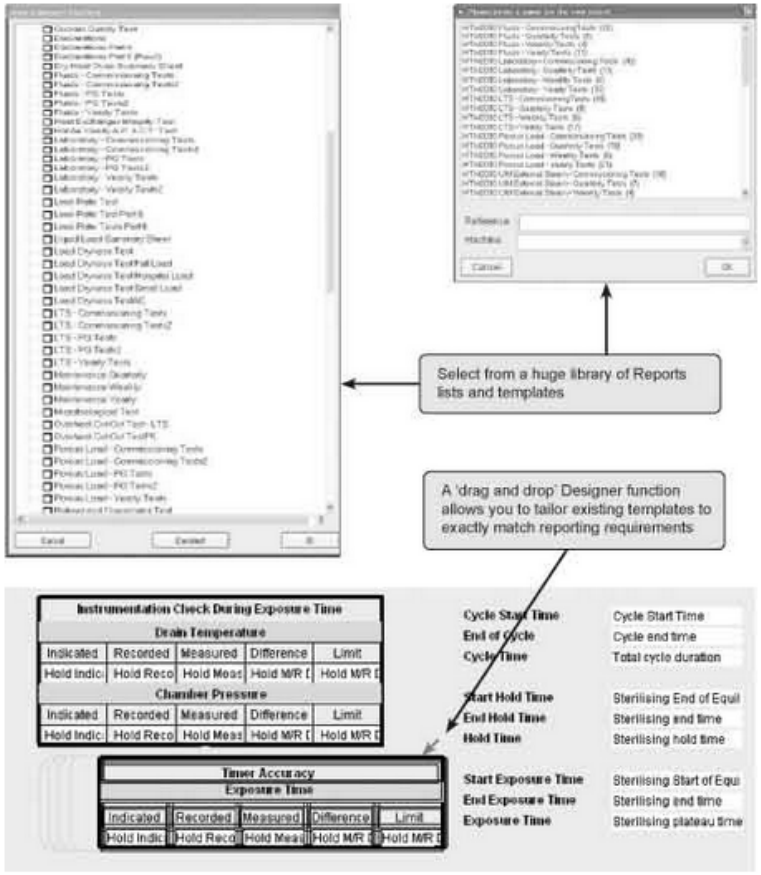
Stability chamber with Test sensors
- Type T thermocouples

- 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

TQSoft: 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

TQSoft and TQAero Ordering Information

Model Number	Description	What's included
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. 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	A set of TQSolutions documents on CD summarizing TQSoft system acceptance testing to GAMP standards.