

**TQSoft is a data acquisition software system designed for the validation of steam or dry heat sterilisers, and other thermal processes and can include pressure and humidity.**

For use in Pharmaceutical and Biotech industries, by Hospitals, Healthcare and associated organisations, it is specifically designed to provide validation data for cGxP audit and process optimisation.



**CFR21 Part 11 driver for Fluke  
1586A and DAQ-STAQ**



TQSoft operates under Windows platforms (pg 19), communicating directly via serial port, USB or ethernet with a variety of data acquisition devices.

TQSoft is a total qualification, reporting AND documentation system that will immediately deliver process and productivity benefits to YOUR operations.

Whatever your current qualification procedures, TQSoft can simplify, streamline, and reduce the cost of your validation operation.

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## **A basic knowledge of Windows is all you need!**

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### **Benefits of using TQSoft include:**

- Simple Windows interface requiring minimal training
- No application or any other programming requirement
- Automated sensor calibration with calibration report archiving
- Interfaces to multiple logging equipment suppliers
- Interfaces to multiple calibration equipment suppliers
- Simultaneous real time trend and digital display
- Historical trend and tabular data displays
- Automatic test data archiving
- Customised reporting (integrates existing SOP report formats!)
- Electronic validation report compilation and archiving
- Acrobat PDF file creation for Electronic distribution and storage
- Electronic signatures, audit trail and security, compliant with CFR21 (see p.7)
- Complete GAMP structured Software Validation Documentation

**(See pages 18 & 19 for complete equipment compatibility lists)**



**CFR21 Part 11 driver  
for Fluke 2638A**



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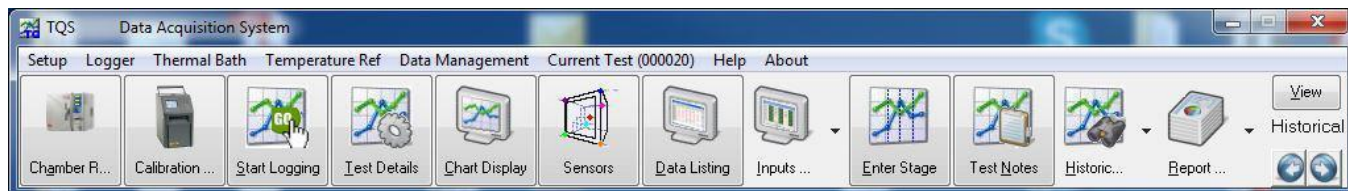
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## The Thermal Qualification System

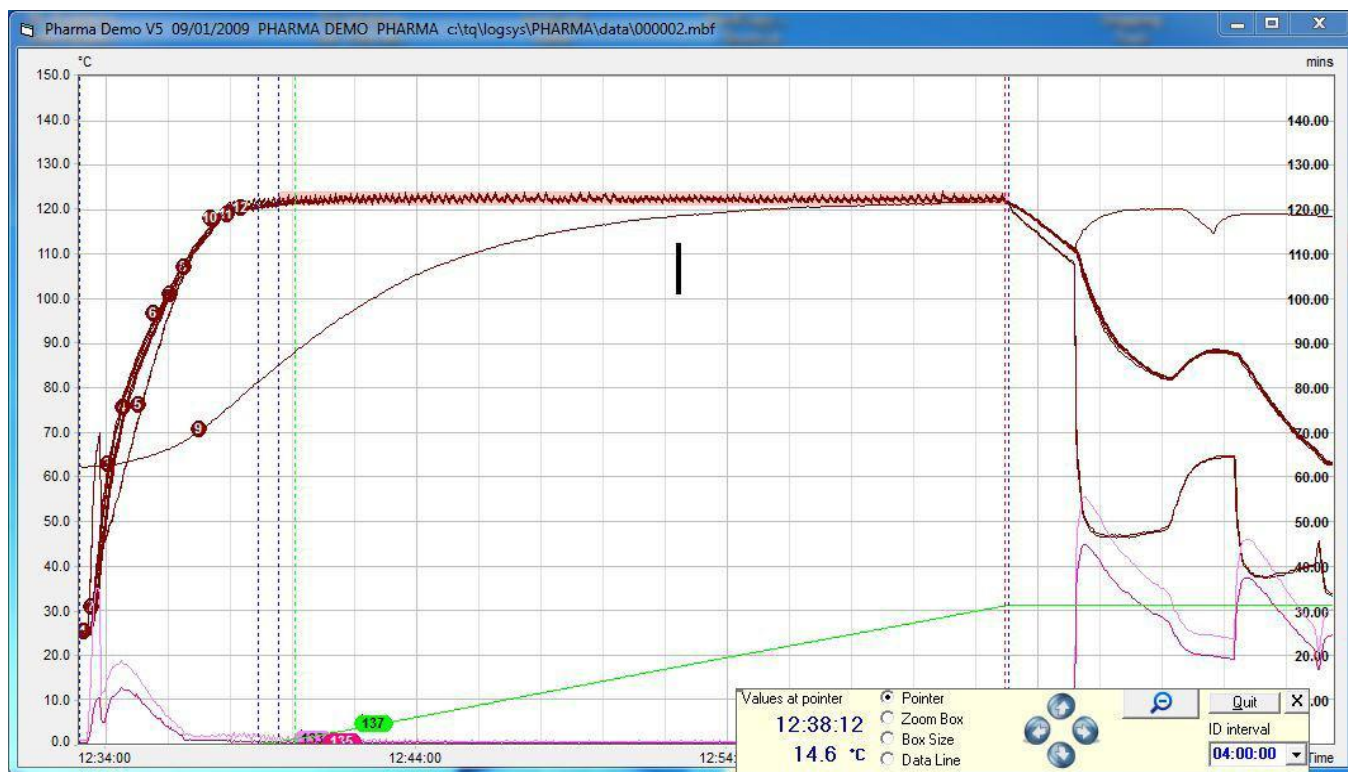
**TQSoft has all the features essential for process monitoring!**

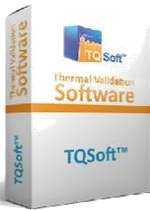
### User-Friendly Menu Display



### Fully Configurable Chart

- Selectable trace ID interval
- Print normal chart or zoom view
- Configurable limit lines
- All individual trace colours are selectable
- Digital values display at vertical time line
- Easily move and resize zoom box with mouse
- Set the number of vertical and horizontal grids
- Real time chart update in normal or zoom view
- Select any probe combo or display calculated variables on graph
- Temperature and Pressure scales on same printout, digital values display
- Plot Max or Min of group
- Option to plot uncertainty





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## Ultra Flexible Data List Matrix

**Tabular Data Listings provide concise data summary of the measured and calculated variables of the tested cycle!**

Colour coded values provide easily recognised timings of limit excursions and attainment of sterilising conditions. User selected critical cycle events and calculations are inserted for reference.

Use Custom Logo

Size of report is determined by user choice. Each "stage" duration has independent data listing frequency control to 1 second resolution.

Options to include any Calculation from TQS unique 'I-Calc' feature.

Stage time events displayed with selectable summary intervals!

Display selected calculations!

Insert any Calculations (I-Calcs)!

Option to show lethalties!

Configurable colours for values above each limit!

List up to 128 channels!

PHARMA DEMO													Page 1 of 7
Cycle No. 000011													24/01/2007
Serial No. PHARMA													23:02:09
c:\logsys\PHARMA\data\000011.mbf													
Pharma Demo V5													The Manufacturing Site
TQSoft Electronic Signature													
Test Person:													
Time	Tmp 1	Tmp 2	Tmp 3	Tmp 4	Tmp 5	Tmp 6	Tmp 7	Tmp 8	Tmp 9	Tmp 10	Tmp 11	Tmp 12	Calculations
	°C	°C	°C	°C	°C	°C	°C	°C	°C	°C	°C	°C	Max-Min Avg-mn
23:02:09	Cycle Started												
23:02:10	25.3	24.6	24.4	24.3	25.1	24.3	24.8	24.7	62.3	24.7	24.7	24.9	38.0 3.5
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	
23:04:10	75.3	88.4	88.7	85.8	75.7	89.1	85.0	85.6	64.3	88.4	87.7	86.0	24.8 18.9
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	
23:06:10	114.0	113.6	114.1	112.6	114.2	114.2	113.1	113.0	70.9	113.9	113.1	113.6	43.3 39.1
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	
23:07:48	Equilibration Start												
23:07:48	121.0	119.5	120.5	119.8	121.5	120.0	119.5	119.7	80.3	120.3	119.8	120.0	41.2 38.5
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	
23:07:52	121.8	120.7	120.9	120.2	121.4	120.9	120.6	120.6	80.9	121.0	120.4	120.8	40.9 38.6
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	
23:07:58	Lethality Start : 121.2 °C												
23:07:58	122.4	121.0	121.0	120.5	122.7	121.2	120.9	120.8	81.4	121.0	120.4	121.3	41.3 38.5
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	
23:08:04	121.2	120.4	121.1	120.6	121.4	120.5	120.4	120.6	82.0	121.1	120.6	120.7	39.4 35.6
	0.12	0.10	0.10	0.09	0.11	0.10	0.10	0.10		0.10	0.09	0.10	
23:08:10	122.0	121.0	121.2	120.7	121.6	121.1	121.0	121.0	82.7	121.3	120.8	121.2	39.3 35.3
	0.25	0.19	0.20	0.18	0.25	0.20	0.19	0.19		0.21	0.18	0.20	
23:08:16	121.7	120.5	121.0	120.5	122.4	120.7	120.5	120.6	83.2	120.8	120.4	121.0	39.2 34.6
	0.36	0.28	0.31	0.27	0.36	0.29	0.28	0.28		0.31	0.27	0.30	
23:08:22	121.3	120.6	121.1	120.7	121.0	120.7	120.7	120.8	83.7	121.2	120.8	121.0	37.6 34.1
	0.48	0.38	0.41	0.37	0.48	0.39	0.38	0.38		0.41	0.37	0.40	
23:08:28	122.7	121.5	121.3	120.9	122.4	121.5	121.5	121.2	84.4	121.3	120.9	121.6	38.3 34.0
	0.61	0.49	0.51	0.46	0.62	0.50	0.49	0.48		0.52	0.46	0.51	
23:08:34	121.5	120.6	121.2	120.8	121.7	120.7	120.8	120.9	84.8	121.2	120.9	121.0	36.9 33.2
	0.73	0.58	0.62	0.56	0.73	0.59	0.59	0.58		0.62	0.56	0.61	
23:08:36	Sterilisation Start : 121.1 °C (Tmp 4)												
23:08:38	Min Sensor Overall : 85.0 °C (Tmp 9)												
23:08:48	122.7	121.7	121.5	121.2	122.4	121.6	121.7	121.5	86.0	121.5	121.2	121.8	36.7 32.7
	1.00	0.80	0.84	0.78	0.99	0.81	0.81	0.80		0.85	0.77	0.85	
23:08:56	123.3	122.2	121.8	121.5	122.8	122.1	122.3	122.0	86.9	121.9	121.5	122.3	36.4 32.3
	1.22	0.99	1.03	0.94	1.22	1.00	1.00	0.98		1.04	0.95	1.04	
23:09:06	Start Calculations												
23:09:06	Max Deviation All Sensors : 0.7 °C												
23:09:06	122.1	121.7	121.7	121.4	121.7	121.6	121.8	121.7	87.9	121.9	121.6	121.9	34.2 31.0
	1.45	1.18	1.23	1.12	1.43	1.19	1.20	1.18		1.24	1.14	1.24	
23:09:16	121.8	121.7	121.8	121.4	121.5	121.5	121.7	121.7	88.7	121.9	121.6	121.8	33.2 30.2
	1.67	1.37	1.42	1.30	1.64	1.38	1.39	1.37		1.44	1.33	1.45	
23:09:26	122.0	121.2	121.7	121.4	122.2	121.4	121.4	121.4	89.7	121.7	121.6	121.7	32.5 29.3
	1.89	1.66	1.62	1.49	1.86	1.67	1.59	1.56		1.84	1.62	1.85	
23:09:34	Min Sensor 1 : 121.4 °C (Tmp 1)												
23:09:34	121.6	121.4	121.7	121.4	121.3	121.2	121.5	121.5	90.4	121.8	121.6	121.6	31.4 28.5
	2.07	1.72	1.78	1.64	2.03	1.72	1.75	1.72		1.80	1.68	1.82	
23:09:38	Min Sensor 2 : 121.0 °C (Tmp 2)												
23:09:38	Min Sensor 3 : 121.5 °C (Tmp 3)												

- Stage event logging
- Configurable user colours
- Temperature summary
- Lethality management
- Calculated value display
- Logs up to 128 channels
- Location of max/min
- Include or exclude sensors





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## Calibration & Calibration Checking

**The open concept of TQSoft provides great flexibility with sensor calibration!**

Fully automatic, operator free procedures are available with a range of equipment from different manufacturers, enabling continued use of existing assets. Temperatures, pressures or other types are similarly calibrated.

### Automatic or Manual Calibration

Sensor calibration is simple with TQSoft. Enter your stability and deviation criteria

and let TQSoft do the rest. When sensors and reference are detected stable as defined, TQSoft automatically applies all correction offsets, and produces an error analysis and repeatability display.

**Calibration setpoints**

**Calibration or post test validation**

The 'Calibration Set Up' dialog box contains the following fields and options:

- Setpoints:** Low Point (20.0), High Point (134.0), Check Point (100.0)
- Stability:** 0.2 Degrees per minute for 5 minutes
- Allowed deviation from Reference:** 0.2
- Reference stability criteria:** 0.05 °C for 1 minute
- Report after Calibration to:** 5 minutes
- Report Interval:** 30 seconds
- Options:** ☐ Automatic, ☐ Calibration Check, ☒ Calibration
- Source of Reference Value:** ☐ Use Reference Probe, ☐ Use Bath Controller, ☒ Use Entered Setpoint(s)

**Sensor and**

It simultaneously generates and archives **reference stability** a full and traceable calibration report.

Post test calibration verification is similarly automated, with up to 5 separate check points selectable.

**In automatic mode, TQSoft will wait until both these countdowns are zero before applying calibration factors**

The 'Auto Calibration Progress' dialog box displays the following table:

	Channel No.	Value	Countdown on Stability Requirements	Biggest Drift this Countdown	Deviation from Reference
Slowest to Stability	3	135.00	02:22	0.02	1.00
Largest Deviation	1	135.02			1.02
Reference Channel	-	134.00	00.00	0.00	

Buttons: ABORT, PROCEED

**Least stable channel and the channel with the largest deviation are displayed**

**The actual reference value is entered here. In full automatic mode this value is read serially from the reference thermometer**



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## Calibration & Calibration Checking (cont.) Data Management & Archiving

### Detailed Calibration Reporting with Uncertainty Management!

- Equipment used listed
- Calibration Certificate Reminders
- Stability analysed
- Status and result summary
- Set-up details as used
- Pre and post calibration error analysis

### Data Management and Archiving

TQSoft provides a Data Management utility to enable simple archiving and maintenance of completed test records. Test and set-up data are archived, copied or deleted without recourse to other operating systems.

Users have the option of archiving at appropriate times or enabling automatic operation during testing.

Data Management also provides backup for Test Specifications, Logger Configurations, Calibration Records and the Machine/Autoclave database.

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### Calibration Report

Job Ref.: PHARMA DEMO Thermocouple: 128 Trial  
Operator: Sign: Date: 23/01/2007 dd/mm/yyyy Time: 20:13:12  
Reviewed By: Sign: Date:

EQUIPMENT		Logger / Recorder	Thermal Bath
Manufacturer	Fuke	Hart	
Model	NetDAQ	9170	
Serial No.	12345	23456	
Test House	Fuke	Fuke	
Cert. No.	ABCDE	ABCDE	
Renew Date	1/1/2008	1/1/2008	
Uncertainty	0.2 °C	0.1 °C	

EQUIPMENT		Temp. Ref. Unit
Manufacturer	Hart	
Model	1502A	
Serial No.	34567	
Test House	Fuke	
Cert. No.	ABCDE	
Renew Date	1/1/2008	
Uncertainty	0.02 °C	

EQUIPMENT Total Measuring Chain Uncertainty 0.32 °C Root Summed Square (RSS) 0.22 °C

#### STABILITY SET-UP

0.2 Degrees per minute for 1 minutes. Allowed deviation from Reference 0.8 degrees.  
Reference stability criteria 0.02 degrees for 1 minute. Report after Calibration for 1 minutes every 10 seconds.  
Report max deviation allowed 0.05 degrees.

Setpoints	Low	High	Programmed	Reference
			100 °C	100.00 °C
			134 °C	134.00 °C

#### LOW Point 100.00 °C STABILITY REPORT

Start Time: 20:13:58 Time when stability requirements met: 20:15:56 Elapsed time: 00:01:59  
Reference change: 0.00 °C Maximum sensor change over last minute: 0.0 °C

Change (°C)	Chan1	Chan2	Chan3	Chan4	Chan5	Chan6	Chan7	Chan8	Chan9	Chan10	Chan11	Chan12
	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

#### LOW Point 100.00 °C QUALIFICATION REPORT

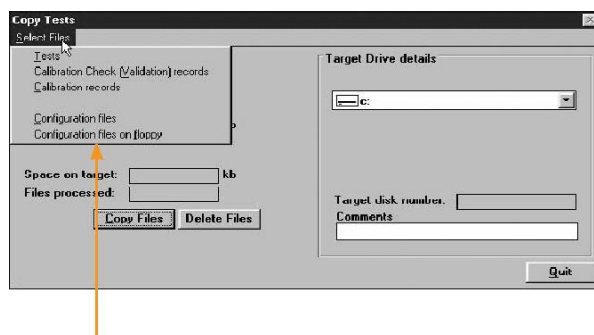
Time	Ref. (°C)	Chan1	Chan2	Chan3	Chan4	Chan5	Chan6	Chan7	Chan8	Chan9	Chan10	Chan11	Chan12
20:15:56	100.00	100.1	100.2	100.2	100.1	100.1	100.1	100.0	100.0	100.2	100.0	100.1	100.1
Deviation (°C)		0.1	0.2	0.2	0.1	0.1	0.1	0.1	0.0	0.2	0.0	0.1	0.1

#### LOW Point 100.00 °C POST CALIBRATION REPORT

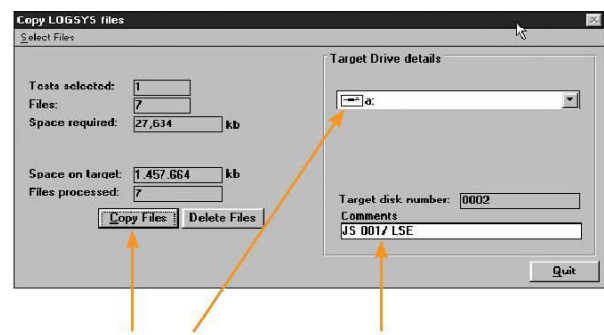
Time	Ref. (°C)	Chan1	Chan2	Chan3	Chan4	Chan5	Chan6	Chan7	Chan8	Chan9	Chan10	Chan11	Chan12
20:16:07	100.00 °C	100.1	100.0	100.0	99.9	100.1	100.1	100.0	100.3	100.1	100.2	100.0	100.2
Deviation (°C)		0.1	0.0	0.0	-0.1	0.1	0.1	0.0	0.3	0.1	0.2	0.0	0.2
20:16:17	100.00 °C	100.1	99.9	100.1	99.9	100.1	100.0	100.0	100.2	99.8	100.0	100.1	99.9
Deviation (°C)		0.1	-0.1	0.1	-0.1	0.1	0.0	0.0	0.2	-0.2	0.0	0.1	-0.1
20:16:27	100.00 °C	100.1	100.0	100.0	100.0	100.0	100.1	100.1	100.1	100.0	100.2	100.0	100.1
Deviation (°C)		0.1	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.0	0.2	0.0	0.1
20:16:37	100.00 °C	100.0	99.9	100.0	100.0	100.1	100.0	100.1	100.1	100.0	100.2	100.0	100.0
Deviation (°C)		0.0	-0.1	0.0	0.0	0.1	0.0	0.1	0.1	0.0	0.2	0.0	0.0
20:16:47	100.00 °C	100.1	99.8	100.0	100.2	100.2	100.0	100.2	100.2	100.0	100.1	100.2	100.2
Deviation (°C)		0.1	-0.2	0.0	0.2	0.2	0.0	0.2	0.2	0.0	0.1	0.2	0.2
MAX DEV. (°C)		0.1	-0.2	0.1	0.2	0.2	0.1	0.2	0.3	-0.2	0.2	0.2	0.2

#### HIGH Point 134.00 °C STABILITY REPORT

Start Time: 20:17:00 Time when stability requirements met: 20:20:18 Elapsed time: 00:03:18  
Reference change: 0.00 °C Maximum sensor change over last minute: 0.0 °C



Choose to archive TEST, CALIBRATION RECORDS or CONFIGURATIONS



Choose TARGET Each archive media drive for copy then given unique ID COPY or DELETE and reference



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## 21CFR Part 11 & Audit Trail Management

**TQSoft provides a full suite of controls and features allowing encrypted security management and enabling Electronic Signature and Audit Trail logging!**

The Security Settings dialog box has tabs for Operator, Hardware, Setup, Test Spec, and Tests. The Operator tab is active, showing a list of operators with 'Demo' selected. On the right, there are fields for 'New Name', 'Add to List', 'De-Activate', and 'Renew Password'. Below these are 'Password Controls' with fields for 'Password and ID Min Length' (5), 'Password Age Limit (days)' (90), and 'Inactivity Timeout' (00:00:00). An 'OK' button is at the bottom right.

**The audit trail is updated automatically by TQSoft.** TQSoft will not run if the audit trail is disabled in any way. Audit trail records and lists every relevant data modification made by the operator and allows reason entry, and records details of changes made, and archives files for restore!

TQSoft even has **Audit Trail maintenance, management and archive functions!**

The TQSAuditForm window displays a table of audit trail records. The table has columns for ID, Name, Date, Time, Action, Operator, Machine Serial, Cycle Number, and File name. A calendar for June 2001 is visible on the right side of the window.

ID	Name	Date	Time	Action	Operator	Machine Serial	Cycle Number	File name
2320	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2321	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2322	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2323	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2324	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2325	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2326	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2327	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2328	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2329	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2330	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2331	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2332	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2333	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2334	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2335	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2336	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2337	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2338	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2339	Demo	31/05/2001	17:56	Security	Operator Access Change TestBake			c:\logsys\operat2.ini
2340	Demo	31/05/2001	17:56	Program Exit				
2341	Demo	31/05/2001	17:59	Program Exit				
2342	Demo	31/05/2001	18:00	Security	Operator Deleted: Ted Baker			c:\logsys\operat2.ini
2343	Demo	31/05/2001	18:00	Security	Operator Access Change Demo: He			c:\logsys\operat2.ini
2344	Demo	31/05/2001	18:00	Security	Operator Deleted: New3			c:\logsys\operat2.ini
2345	Demo	31/05/2001	18:00	Program Exit				
2346	Richard Bridger	01/06/2001	09:47	Security	ID and Password setup			
2347	Richard Bridger	01/06/2001	09:47	Security	Logged In			
2348	Richard Bridger	01/06/2001	09:49	Security	Logged In			
2349	test1	01/06/2001	10:31	Security	Operator Added: test1			c:\logsys\operat2.ini
2350	test1	01/06/2001	10:32	Security	Operator Added: test2			c:\logsys\operat2.ini
2351	test1	01/06/2001	10:32	Security	Operator Added: test3			c:\logsys\operat2.ini
2352	test3	01/06/2001	10:32	Security	ID and Password setup			
2353	test3	01/06/2001	10:32	Security	Logged In			
2354	test3	01/06/2001	10:33	Security	Operator Deleted: test1			c:\logsys\operat2.ini
2355	test3	01/06/2001	10:33	Security	Operator Deleted: test2			c:\logsys\operat2.ini



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## I-Calcs: The Perfect Innovative Solution for Calculations

**I-Calcs are the latest innovation from TQSoftware that fits validation requirements perfectly!**

- NEW! I-Calc Wizard helps quickly setup complex I-Calcs
- NEW! Copy and paste and I-Calc management tools
- I-Calcs allow users to insert event 'stages' into Data Listings, Charts, Reports
- I-Calcs duplicate the power of spreadsheet functions, but within the context of TQSoft CFR21 Part 11 compliance
- Then use the stages as start and stop markers for lethality, max, min, average, fluctuation, deviation etc. on any group of sensors
- Allows you to insert the calculation results into Data Listings, Charts, Reports
- Then, it even allows you to set up limits on calculation results and highlight out of specification results
- TQSoft comes with a library of pre-configured calculations for your use

00:29:46	121.9	121.9	121.9	121.7	121.7	121.6	122.2	122.1	121.7	122.1
	32.83	32.43	32.03	30.98	31.73	30.84	33.75	32.87		32.83
00:29:55	End Calculations : 123.9 °C (Tmp 5) [INT:05:00 CODE:01]									
00:29:55	122.2	122.2	122.2	122.1	122.0	121.9	122.5	122.4	121.9	122.3
	33.04	32.64	32.24	31.19	31.93	31.04	33.97	33.09		33.04
00:29:56	Max Load Temperature Hold Time Fluctuation : 3.4 °C (Tmp 7) [INT:00:00 CODE:54]									
00:29:56	Max average : 122.4 °C (Tmp12) [INT:00:00 CODE:55]									
00:29:56	Min average : 122.1 °C (Tmp 6) [INT:00:00 CODE:55]									
00:29:56	Max Fluctuation : 3.8 °C (Tmp 2) [INT:00:00 CODE:55]									
00:29:56	122.0	122.1	122.1	121.9	121.8	121.9	122.4	122.2	121.9	122.2
	33.06	32.66	32.26	31.21	31.95	31.06	33.99	33.11		33.07
00:30:04	Sterilisation End : 120.9 °C (Tmp 5) [INT:05:00 CODE:14]									
00:30:04	121.4	121.5	121.4	121.2	121.1	121.1	121.7	121.0	121.5	121.0
	33.22	32.82	32.42	31.36	31.10	31.21	34.17	33.28		33.23
00:30:05	Hold Time Duration : 00:23:33 hh:mm:ss [INT:00:00 CODE:55]									
00:30:05	Exposure Time Duration : 00:25:15 hh:mm:ss [INT:00:00 CODE:55]									
00:30:05	121.2	121.5	121.5	121.3	120.9	121.2	121.7	121.6	121.6	121.6

**Fantastic Functionality at your Fingertips!**

These calculations can even be inserted into a test setup AFTER the test has been run. They do not affect measured data. Allows you unparalleled power to analyse and present your validation work.

First Load Location to reach S.T.	T/C	5	Location:	Location 5
Last Load Location to reach S.T.	T/C	4	Location:	Location 4
Average Hottest Load Location	T/C	12	Location:	Location 12
Average Coldest Load Location	T/C	6	Location:	Location 6
Maximum load Temperature measured	T/C	7	124.4 C	Limit (ST + 3Deq)
Minimum load Temperature measured	T/C	6	121.0 C	Limit
Maximum load Temperature Difference (Excl. discard)			3.4 C	Limit
Max load Temp. fluctuation (with offsets)	T/C	7	124.4 C	Limit





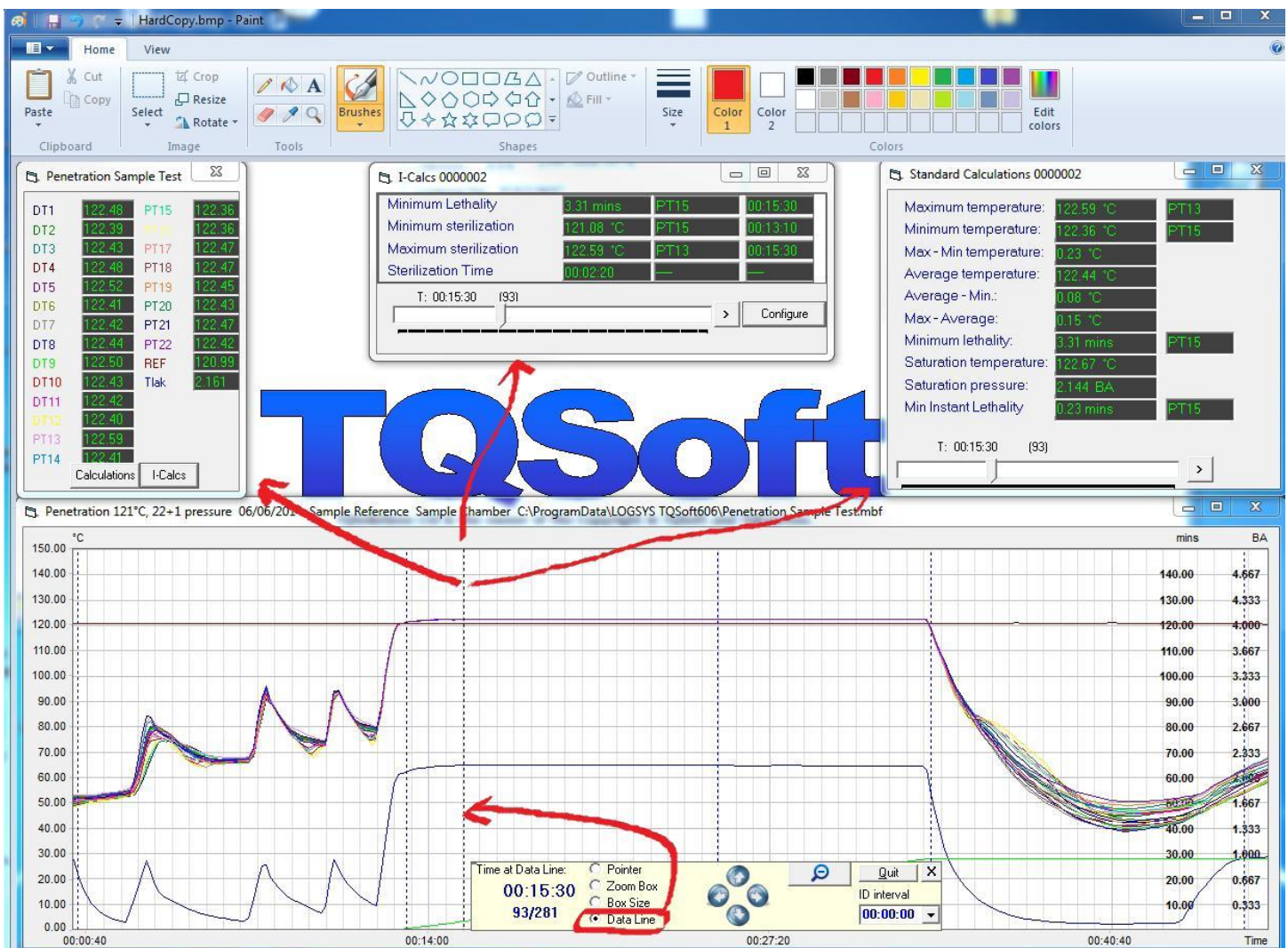
# TQSoft

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 Real Time &  
Historic Calculations Display

**Now TQSoft can show all its standard calculations and configure I-Calcs in real time!**

- When test is finished the calculations can be replayed using the chart Data Line as a slider
- Then, I-Calcs can be added, modified, or deleted, and the test replayed with the new settings
- Perfect analysis tool for all kinds of validation
- Powerful, easy, and **21CFR Part 11 compliant**



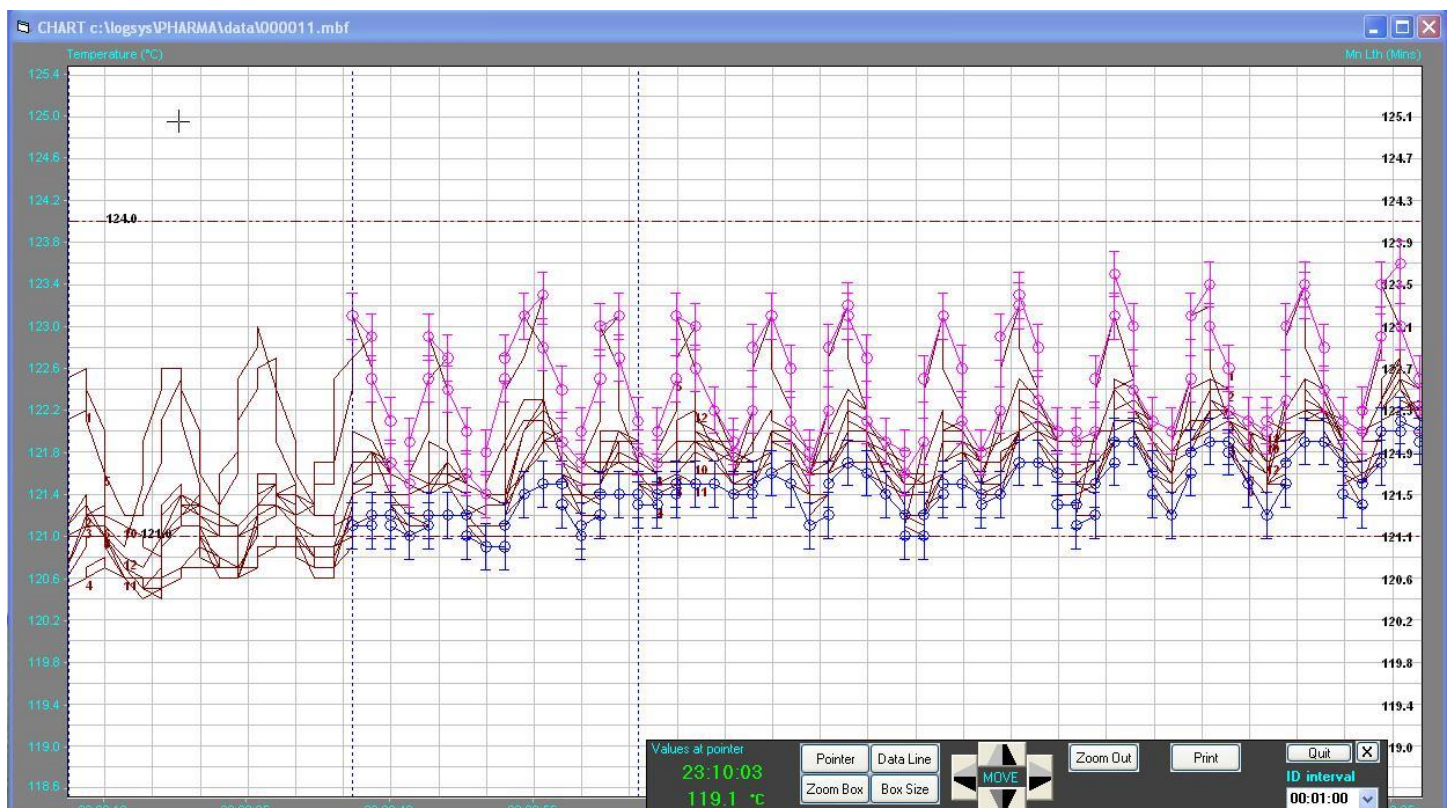


**Any Quality measurement system should know and display its Uncertainty!**

Enter your uncertainty values into the TQSoft Test Equipment Database and let TQSoft do the rest!

EQUIPMENT	Logger / Recorder	Thermal Bath
Manufacturer	Fluke	Hart
Model	NetDAQ	9170
Serial No.	12345	23456
Test House	Fluke	Fluke
Cert. No.	ABCDE	ABCDE
Renew Date	1/1/2008	1/1/2008
Uncertainty	0.2 °C	0.1 °C
EQUIPMENT	Temp. Ref. Unit	
Manufacturer	Hart	
Model	1502A	
Serial No.	34567	
Test House	Fluke	
Cert. No.	ABCDE	
Renew Date	1/1/2008	
Uncertainty	0.02 °C	
<b>EQUIPMENT Total Measuring Chain Uncertainty 0.32 °C</b>		<b>Root Summed Square (RSS) 0.22 °C</b>

**Uncertainty is fully reported on Calibration Reports and Optional on other TQSoft Reports. There is even an option to display the Uncertainty on a Chart.**





# TQSoft

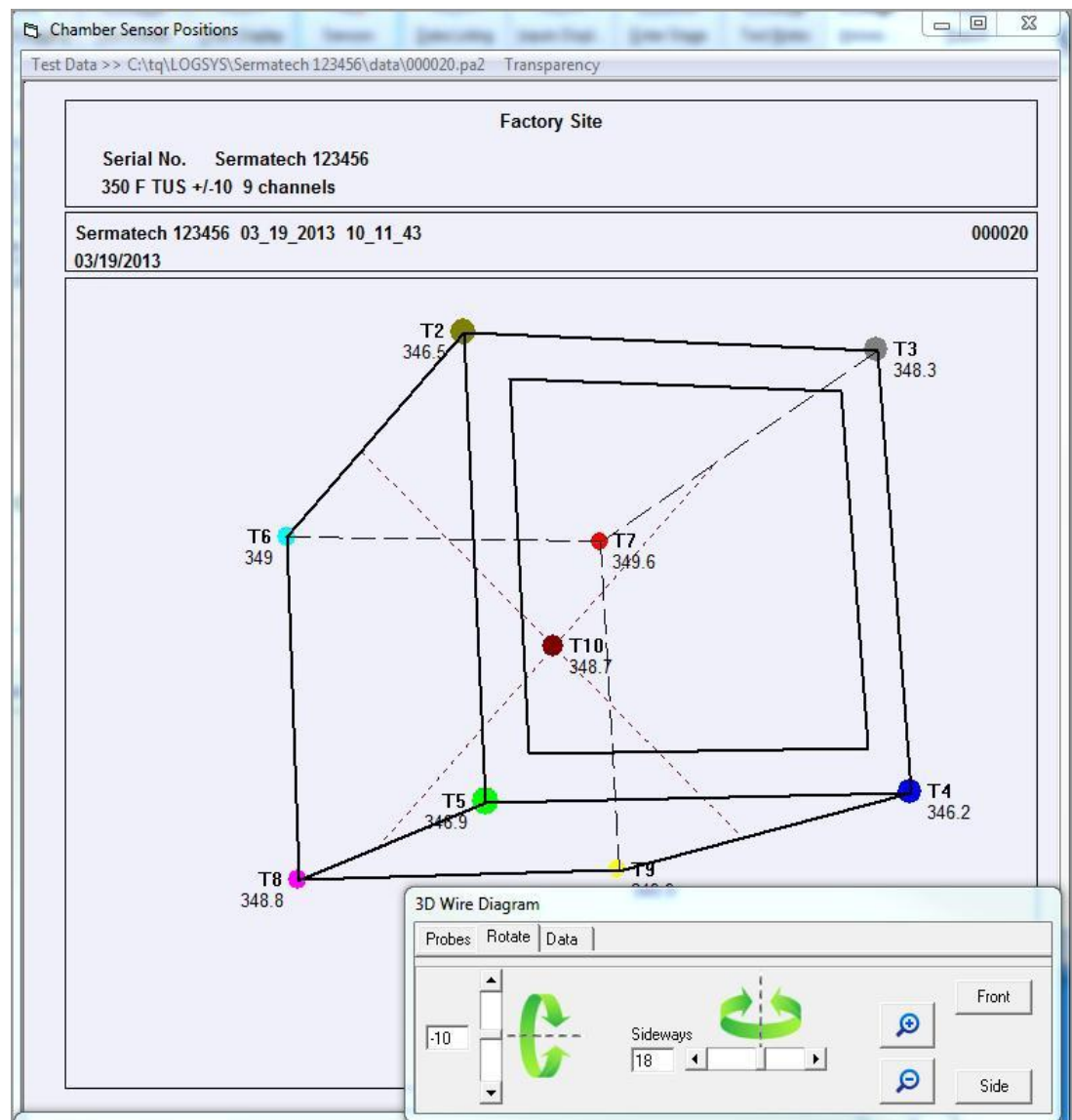
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## Sensor Position Management

**TQSoft now allows validation engineers to setup and manage a 3D wire diagram of the chamber space!**

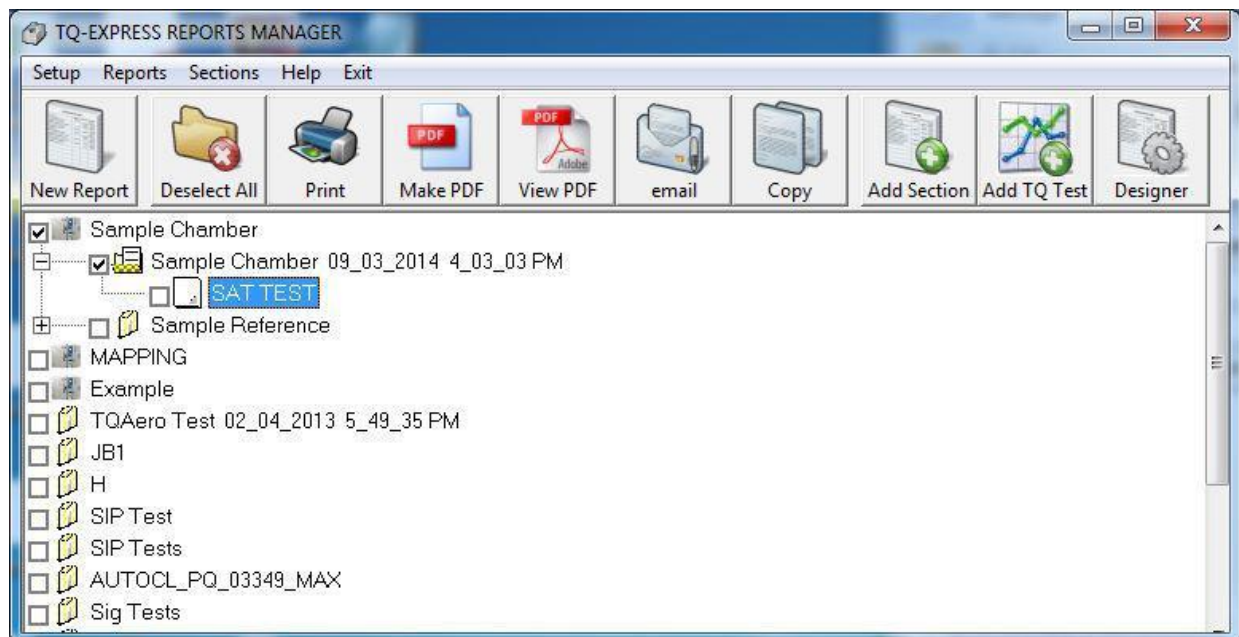
- Drag and drop sensors to their correct position in 3D space
- Completed position diagram can be rotated and magnified
- Option for real time display of measurement values in the diagram
- Option to represent temperature gradients with color shading at each sensor position
- When test is complete the real time display can be replayed with a time slider, showing temperature behaviour and anomalies in the chamber
- Completed diagrams are easily added to reports.





**As a result of TQSoftware's co-operation with and support for leading validation professionals, TQExpress is ideally suited to validation and data acquisition requirements!**

- Contains a huge library of report templates for all processes
- Reports can be tailored to the needs of individual organisations, processes and equipment
- Exactly replicate existing S.O.P. formats
- Reports are of presentation quality, instantly produced, easily managed and secure
- Reports can include graphics, complex calculations based on acquired test data, lethality formulae, and engineering lookup tables
- The calculations and lookup tables are validatable
- Designer & editor included - no need for word processors
- Work in any language



**Contact Us TODAY for a free trial!**

**Ph: UK: +44 (0)871 2182881 | Outside UK: +1-250-545-7750 | Email: [info@tqsolutions.net](mailto:info@tqsolutions.net)**





On top of the existing unrivalled library of HTM2010 and HTM2030 report formats TQSoft has added a whole new dimension to TQExpress by allowing complete Word document integration!

- Now design your Reports in Word, or use your existing Reports and seamlessly integrate them into TQ-Express for vastly improved management and operational performance
- Now has a hierarchical filing option to make accessing and managing reports as efficient as possible

Highlighted items are filled in automatically by TQExpress

### Porous Load Sterilizer Annual Test Record

#### THERMOMETRIC TEST FOR A SMALL LOAD

Cycle No: **XXXX**

Channel	Location	Holding Time Temperature				Time above 134°C
		Start	1minute	2minutes	3minutes	
<b>CH1</b>	Drain	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH2</b>	Load	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH3</b>	Top Sheet	Max Temp <b>XXXX</b> °C	Temp 1 minute into plateau period <b>XXXX</b> °C			
<b>CH4</b>	Pressure	<b>XXXX</b> bar	<b>XXXX</b> bar	<b>XXXX</b> bar	<b>XXXX</b> bar	
Equilibration Time						<b>XXXX</b> mins.secs
Dryness of Test Sheets						Satisfactory / Unsatisfactory (delete as appropriate)

#### THERMOMETRIC TEST FOR RE-QUALIFICATION

Cycle No: **XXXX**

Channel	Location	Holding Time Temperature				Time above °C
		Start	minute(s)	minutes	minutes	
<b>CH1</b>	Drain	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH2</b>	Load	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH3</b>	Free Space	Max Temp <b>XXXX</b> °C	Temp 1 minute into plateau period <b>XXXX</b> °C			
<b>CH4</b>	Pressure	<b>XXXX</b> bar	<b>XXXX</b> bar	<b>XXXX</b> bar	<b>XXXX</b> bar	
Equilibration Time						<b>XXXX</b> mins.secs
Dryness of Test Sheets						Satisfactory / Unsatisfactory (delete as appropriate)

#### THERMOMETRIC TEST FOR RE-QUALIFICATION

Cycle No:

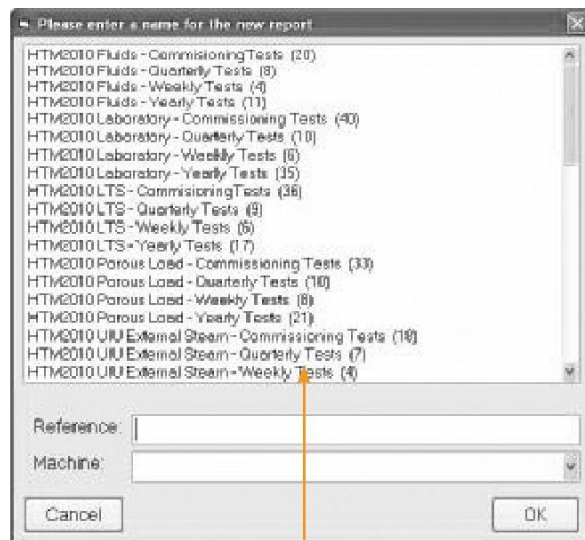
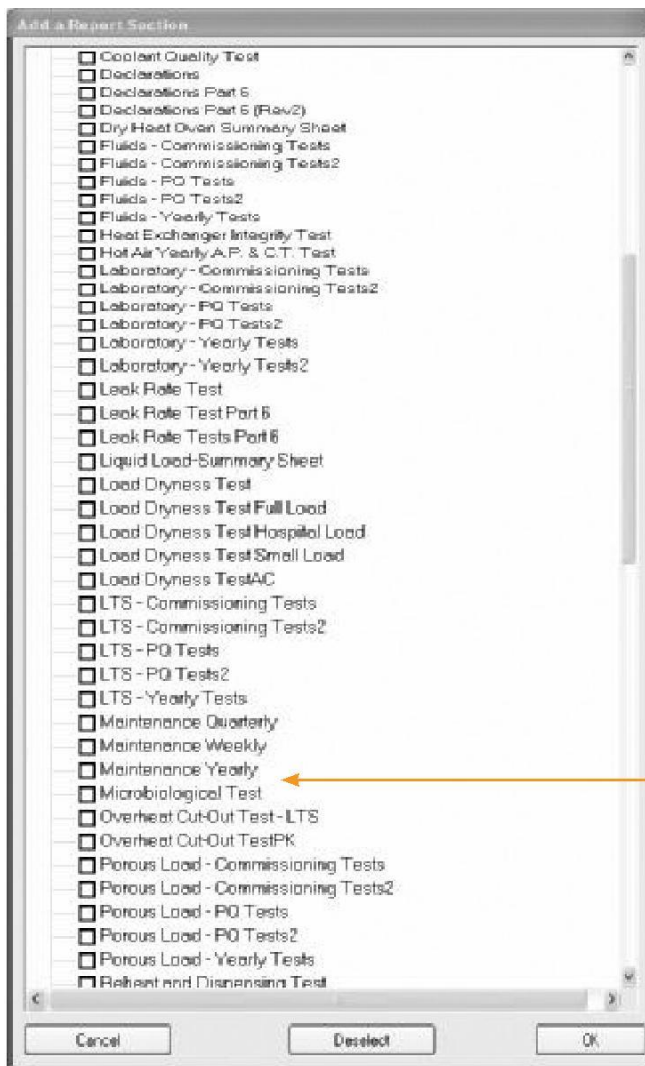
Channel	Location	Holding Time Temperature				Time above °C
		Start	minute(s)	minutes	minutes	
<b>CH1</b>	Drain	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH2</b>		<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH3</b>		<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH4</b>		<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH5</b>		<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
<b>CH6</b>		<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> °C	<b>XXXX</b> mins.secs
		Max Temp <b>XXXX</b> °C	Temp 1 minute into plateau period <b>XXXX</b> °C			
Pressure		<b>XXXX</b> bar	<b>XXXX</b> bar	<b>XXXX</b> bar	<b>XXXX</b> bar	
Equilibration Time						<b>XXXX</b> mins.secs
Dryness of Load						Satisfactory / Unsatisfactory (delete as appropriate)



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## TQExpress: Template Library



Select from a huge library of Reports lists and templates

A 'drag and drop' Designer function allows you to tailor existing templates to exactly match reporting requirements

Instrumentation Check During Exposure Time				
Drain Temperature				
Indicated	Recorded	Measured	Difference	Limit
Hold Indic:	Hold Reco	Hold Meas	Hold M/R [	Hold M/R [

Chamber Pressure				
Indicated	Recorded	Measured	Difference	Limit
Hold Indic:	Hold Reco	Hold Meas	Hold M/R [	Hold M/R [

Timer Accuracy				
Exposure Time				
Indicated	Recorded	Measured	Difference	Limit
Hold Indic:	Hold Reco	Hold Meas	Hold M/R [	Hold M/R [

<b>Cycle Start Time</b>	Cycle Start Time
<b>End of Cycle</b>	Cycle end time
<b>Cycle Time</b>	Total cycle duration
<b>Start Hold Time</b>	Sterilising End of Equil
<b>End Hold Time</b>	Sterilising end time
<b>Hold Time</b>	Sterilising hold time
<b>Start Exposure Time</b>	Sterilising Start of Equi
<b>End Exposure Time</b>	Sterilising end time
<b>Exposure Time</b>	Sterilising plateau time



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## TQExpress: Additional Features

**TQExpress offers an alternate and supplementary method of report archiving and distribution!**

### PDF Creation



- A simple click on the appropriate Icon will convert an electronically assembled report to an Adobe Acrobat PDF document. The report can now be independently archived and is immediately available for transmission by E-Mail or other networks. A complete validation document is now able to be read by anyone with the freely available Acrobat Reader.

### Mix TQSoft Reports, Word Docs and Templates



- Add Charts, Zoom Region, Data Listings, Calibration Reports, Notes and more to a full report listing in SVReports
- Add any templates and Word documents and then print or convert the entire list of report sections to one PDF!

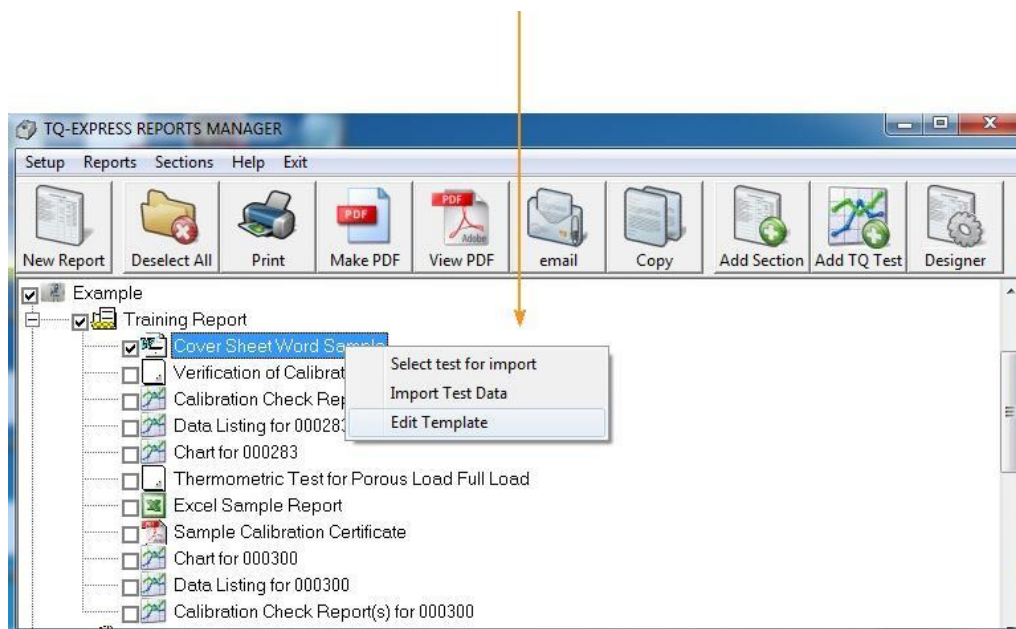
### ZIP and E-mail Reports



- The email option allows you to ZIP and immediately email a report as an attachment
- Options to attach PDF, Report files, original data files
- Its so simple and efficient for communicating or archiving reports or data

### Full Management of Your Word Document Templates

- TQExpress allows you maintain a folder for Word templates
- When you use the template a copy is made, but you can easily edit the original template too



## Schedule of Validation Tests HTM2010\*

- Porous Load sterilizers
- Sterilizers for unwrapped instruments and utensils
- Laboratory sterilizers
- LTS disinfectors and LTSF sterilizers
- Fluid sterilizers

## Schedule of Periodic Tests

### Porous Load sterilizers

- Yearly tests\*
- Quarterly tests
- Weekly tests

### Sterilizers for unwrapped instruments and utensils

- Yearly tests\*
- Quarterly tests
- Weekly tests

### Laboratory sterilizers

- Yearly tests\*
- Quarterly tests
- Weekly tests

### LTS disinfectors and LTSF sterilizers

- Yearly tests\*
- Quarterly tests
- Weekly tests

### Fluid sterilizers

- Yearly tests\*
- Quarterly tests
- Weekly tests

\*Includes duplicate of summary sheets published in HTM2010. Summary sheets are automatically completed as test reports are completed.

## Schedule of Validation Tests HTM2030

- Generic
- Endoscopes
- Hollowware
- Human Waste
- Surgical Instruments
- Ultrasonics

## Schedule of Periodic Tests

### Generic

- Yearly tests
- Quarterly tests
- Weekly tests
- Daily tests

### Endoscopes

- Yearly tests
- Quarterly tests

### Hollowware

- Yearly tests
- Quarterly tests

### Human Waste

- Yearly tests
- Quarterly tests

### Surgical Instruments

- Yearly tests
- Quarterly tests

### Ultrasonics

- Yearly tests
- Quarterly tests



### Custom Reports Design/Modify

- Build complete custom reports using Designer option
- Commission TQSoftware to design or modify reports to suit your precise requirements
- Import any TQSoft I-Calc results into custom reports
- Report Manager allows instant creation of complete report from Report List Template

### Build a Complete Customer Report

- Include any TQSoft report window in the Report list:
  - Test Setup report
  - Data Listing report
  - Charts
  - Calibration reports
  - Calibration Checking reports
  - Operator notes
- Add Word documents as cover sheets, load diagrams etc., include photos in reports

### Convert to PDF Format Option

- Convert entire report list to PDF including:
  - Standard and custom templates
  - TQSoft report windows
  - Word documents etc.

### Management Features

- Lock reports
- Email complete reports with options
  - Zipped up feature
  - Include all test data files
  - Include PDF
- Copy & archive complete reports button





The amazing functionality built into TQSoft and TQExpress is aimed specifically at dedicated Validation Engineers! (some samples below)

### Calculation Functions

- Selectable groups
- Selectable Interval
- Selectable Limits
- Set IO on Limit
- Set Message on Limit
- Set Report colour on Limit
- Select where calculation appears
- Set insert stage event on Limit
- Interval Duration
- Time at Temperature
- Max Group Mean Kinetic Temperature
- Min Group Mean Kinetic Temperature
- Max probe value
- Max Curve Plot
- Min Curve Plot
- Uncertainty Plot
- Min of Maxs
- (Max - Min) Of Maxs
- Min probe value
- Max of Mins
- (Max - Min) Of Mins
- Average probe value
- Max Average
- Min Average
- Fluctuation
- Max Fluctuation
- Max Deviation
- Max lethality
- Min lethality
- Lethality Deviation
- Max per scan
- Min per scan
- Average per scan
- Max-Min per scan
- Max – Average per scan
- Average – Min per scan
- Min Lethality per scan

### Supported Loggers

- Agilent 34970A
- Anville 415
- Anville 425
- Anville 435
- Anville 500
- Eurotherm 4250, 4180
- Eurotherm Series 5000, 5100
- Eurotherm Series 6000, 6100
- ★ Fluke 1586A Super-DAQ Precision Temperature Scanner
- Fluke Hydra 2620A, 2625, 2635
- ★ Fluke 2638A Hydra Series III
- Fluke 2680
- Fluke NetDAQ 2640A, 2645
- ★ Gemini Tiny Tag range
- ★ Grant Squirrel 2040
- ★ Graphtec GL800
- Kaye KL/Portable/Digi
- Kaye Validator 2000
- MadgeTech
- Sterimixer
- Tecno Tempstick & HumiStick
- TMI Orion TYPE 2
- TMI VACQ3000
- Yokogawa DR Range
- Yokogawa DX200P, DX100P
- Yokogawa DX2000,DX1000
- Yokogawa DXP, DX Range
- Yokogawa GP/GX
- ★ Yokogawa MicroR1800
- Yokogawa MV/MX/MW
- ★ Yokogawa MV Range



**Denotes NEW supported loggers**



Requires Windows XP, Windows 7, or Windows 8 and  
?????? MB of hard disc space (some samples below)

### Supported Calibration Hardware

- AMETEK DTI
- AMETEK CTC, ITC, MTC range
- AMETEK RTC/PTC range
- Anville Series 270 Digital
- ASL B Series Calibrator Controller
- ASL F250 MkII Precision
- Beamex FB range
- Cropico 3001
- Fluke 914 X Series
- Fluke/Hart 9190A
- Fluke/Hart 1502A, 1521
- Fluke/Hart Micro 6102, 7102, 7103
- Fluke/Hart 7380 Controller
- Fluke/Hart 9011, 9007, 9150
- Fluke/Hart 9101
- Fluke/Hart 9140, 9009, 9103, 9141
- Fluke/Hart 9170, 9171, 9172, 9173
- Intelligent RTD
- Isotech ISIS
- Isotech TTi6
- Isotech INDICATOR
- Isotech Controller
- Kaye HTR400/LTR140 Controller
- Techne Dry-Block range
- Thermometer
- TESTO 400/650/950

### Lethality Functions

- Standard lethality formula
- Enhanced 'trapezoid' formula
- Selectable channel group
- Start/Stop on selectable stage/temperature
- Start/Stop on pressure correlation limit
- Use pressure correlation for time at temperature Start/Stop

### General Functions

- Test Equipment Database + management
- Operator Database + management
- Tested Machine Database + management
- Audit Trail + management
- Test Specification Database + management
- I-Calc Database + management
- Calibration, Calibration Records Database + management
- Cal Checking, Calibration Checking Records Database + management
- Data List, Test Notes, Chart, Test Setup, I-Calc Report
- Historic Test Database + management

★ Denotes NEW supported calibration hardware

**TQSoftware offers full validation support for its products in keeping with guidelines and methods advocated by the GAMP forum!**

The GAMP Forum is a subcommittee of ISPE, the Leading Global Society for Healthcare Technology Professionals. The GAMP Forum was established by representatives from major international companies, to interpret and improve understanding of regulations regarding the use of automated systems in pharmaceutical manufacturing.

**The documentation available enables compliance with the requirements of EC Directive 356 as explained in the European Guide to Good Manufacturing Practice (GMP), Annex 11 Computerised Systems, and is similarly described by the Parenteral Drug Association.**

By adopting the principles of GAMP 4, both suppliers of automated systems and their customers benefit from improved visibility and understanding of the products, with reduced validation costs and timetables.

TQSoftware offers the following documentation for clients to retain and assist them in their validation obligations:

#### **Requirements and Functional Specifications**

The document is broken into sections generally covering all the sub-systems in the TQSoft application. The software functionality is broken down into small discrete items and numbered, so as to provide the basis for a comprehensive and fully cross referenced test plan.

#### **TQSoft System Acceptance Tests**

This document was created by TQSoftware for the purpose of validating the TQSoft software package according to GAMP4 guidelines, and to provide users with a test plan for their own performance and operational qualification of TQSoft.

#### **Trials/Demos**

Temporary trial evaluation licenses are available on a 'try before you buy' basis. Demonstration videos for TQSoft and the TQExpress are online at [www.tqsoftware.com](http://www.tqsoftware.com).

#### **Support**

TQSolutions offers support contracts for expert email / telephone and on site support of its software package.