

Pharmaceutical, Medical, Healthcare Processes Validation & Monitoring



Application Fields for Processes Monitoring and Instruments Validation

Tecnosoft wide range of temperature and pressure data loggers is suitable for many applications thanks to their design, stainless steel housing, IP68 protection degree

Healthcare / Medical Field

Washer-disinfectors
 Steam Sterilizers
 Freeze Dryers for Lyophilization
 Refrigerators, Freezers, Ultra Freezers
 Laboratories
 Autoclave Mapping and Validation
 Hydrogen Peroxide Autoclave
 Plasma units and sample monitoring



Pharmaceutical Field

Steam Sterilizers
 Autoclave Validation and Mapping
 Freeze Dryers for Lyophilization
 Cold storage
 Incubators
 Refrigerators, Freezers, Ultra Freezers
 Laboratories



Compliance & Standards

Tecnosoft systems are compliant with the relevant standards and guidelines:

ISO 17665	Sterilization of health care products and routine control of a sterilization process for medical devices
ISO 13060	Small steam sterilizers - Manufacturers
ISO 15883	Washer disinfectors - General requirements, terms and definitions and tests
UNI EN 285	Sterilization - Steam sterilizers - Large sterilizers
FDA 21 CFR Part 11	US FDA regulations
GAMP5	Guidelines for good automated manufacturing practice

Temperature, Pressure, Humidity: the data loggers

All loggers are provided with a calibration certificate traceable to a national standard and host a user replaceable battery.



S-MicroW L S-MicroW XL PressureDisk PressureDisk 05 Pirani RHTemp L RHTemp XL

	39 mm	64 mm	43.22 mm	43.22 mm	73 mm	46 mm	71 mm
	20 mm	20 mm	35 mm	35 mm	30 mm	18 mm	18 mm
Probe	Rigid Flexible Bendable	Rigid Flexible Bendable	Rigid radial	-	-	-	-
Battery Life							

S-MicroW L S-MicroW XL Ultra Freeze PressureDisk PressureDisk 05 Pirani RHTemp80 L RHTemp 125 XL

Range	Logger: -40°C ÷ +140°C Probe: -40°C ÷ +500°C (depending on model)	-80°C ÷ +140°C	T: -40°C ÷ +140°C P: 0 bar ÷ 5 bar absolute	T: 0°C ÷ +140°C (operative) P: 0 bar ÷ 5 bar absolute	T: -20°C ÷ 85°C P: 0,001 ÷ 1200 mbar	T: -40°C ÷ +80°C H: 0% ÷ 100% RH (not condensing)	T: -40°C ÷ +125°C H: 0% ÷ 100% RH (not condensing)
Accuracy	± 0,1°C (± 0,05°C upon request)	± 0,1°C (± 0,05°C upon request)	T: ± 0,1°C P: ± 15 mbar	T: ± 0,1°C P: ± 15 mbar	T: ± 0,1°C P: ± 0,0003 mbar (0,005 ÷ 0,01 mbar)	T: ± 0,2 °C (0 °C ÷ +60 °C) / ± 0,5 °C (-20 °C ÷ +80 °C) H: ± 1,8% RH (0% ÷ 80%) @ 23°C	T: ± 0,2 °C (0 °C ÷ +60 °C) / ± 0,5 °C (-20 °C ÷ +125 °C) H: ± 1,8% RH (0% ÷ 85%) / ± 3% RH (85% ÷ 100%) @ 23°C
Resolution	0,01°C	0,01°C	0,02°C	0,02°C	T: ± 0,1°C P: 0,0001 mbar (0,02 ÷ 10 mbar)	T: 0,015 °C H: 0,02%	T: 0,015 °C H: 0,02%



Validation Kit



No matter how big or tough is the job that lays ahead, we will provide you a tailor made kit with the exact number of devices needed to complete it. You can chose any combination of temperature and pressure data loggers, all supplied in an elegant case with the required accessories and software.

The kit includes



- High Temperature Data Loggers with Calibration Certificates
- Pressure Data Loggers with Calibration Certificates
- Humidity Data Loggers with Calibration Certificates
- TS Manager Software, FDA 21 CFR Part 11 and GAMP 5 compliant
- Single or Multiple Reader Station for data downloading and device programming
- Spare batteries for all devices
- Universal Opening Tool for battery change

Reader Stations

DiskInterface HS



USB Reading Base for connecting, downloading data, programming all models of data loggers.



Universal multibay



USB Multiple Reading Base allows to connect, download, program up to 5 data loggers simultaneously.



TS Manager

Validation Software for autoclaves, compatible with **FDA 21 CFR Part 11** regulations.

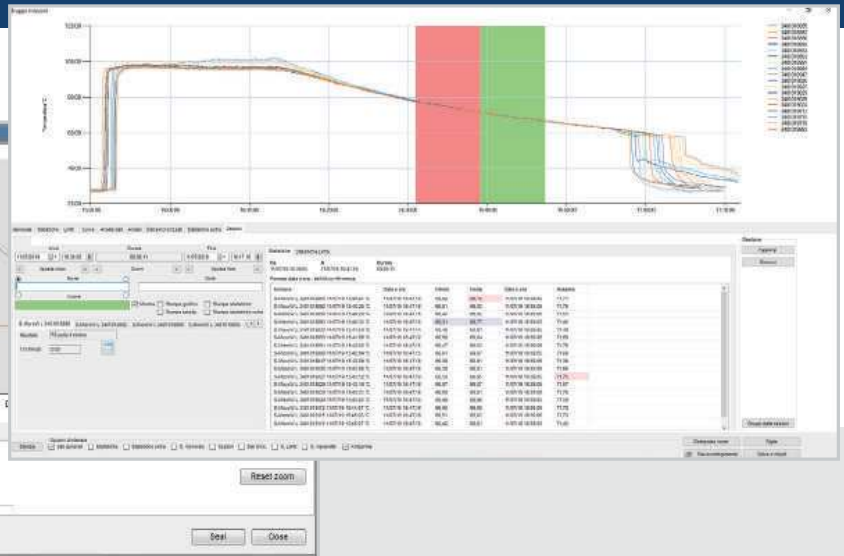
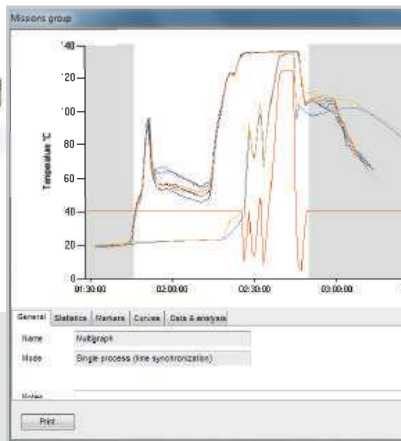
The TS Manager is an advanced validation software developed according to **21 CFR Part 11 and GAMP guidelines**.

The software enables the user to collect, display and analyse validation data from all Tecnosoft high temperature, pressure and humidity devices and has all features and all reports needed for validators of autoclaves, incubators in the healthcare & medical industry.

The intuitive interface of software puts in your hands a powerful tool but very easy to use. Create your database of Customers and Instruments to validate, create validation profiles to analyse the processes, start your loggers and then download them and check all data collected. The IQ/OQ protocols are also available from Tecnosoft.



Software Features

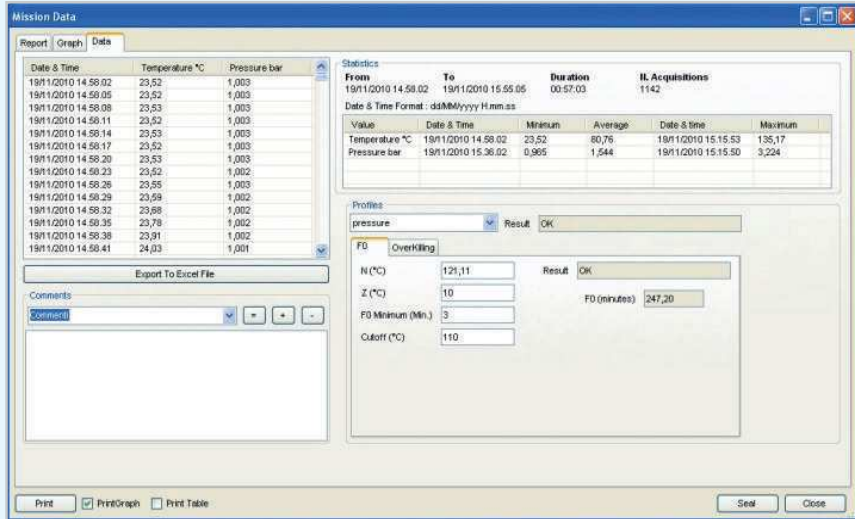


- Data in the devices not editable
- Data in software not editable
- Access for each user through a login and password
- Client/server setup and shared database
- Multi-user access
- Multi-level users, with different functions for each level
- Electronic Signature for report printing
- Customers and validated Instruments database for validators activity
- Audit Trail: recording, not editable, of all carried out operations
- Data analysis through pre-set or customizable parameters
- Possibility of pre and post mission comments
- Visualization in graph, with zoom, and table
- Possibility to generate Analysis Groups from single Sections. You can have more than one test on a graph and divide each test to analyse it separately
- Multi graph analysis
- Graph divided into Sections with analysis and statistics for each section
- Possibility to generate Analysis Groups from single Sections. You can have more than one test on a graph and divide each test to analyse it separately
- Synchronized data table with statistics for each acquisition: maximum, minimum, average, maximum-minimum, maximum-average, average-minimum
- Theoretical temperature calculation based on pressure in saturated steam environment
- Customizable parameters: acquisition step, mission duration, analysis type (lethality with Z and reference temperature values setting, Overkilling for validation, Vacuum Leak Test)
- Print of customizable reports with company logo and layout of the printed sections
- Data and reports export in HTML and XLS (MS Excel) format
- Calculated parameters: Lethality (F0, PU, A0, Vacuum Leak, Maintenance Time, Limits exceeding) Languages: Italian, English, German

Process Analysis

TS Manager offers several tools to analyse your data. A complete **HTML report** is displayed with all the details from your process: type of analysis, result, logger used, operator who programmed and downloaded it, all data acquired.

The **Graph** has zoom feature, vertical and horizontal markers to set points for analysis both on temperature and pressure (you can define a part of graph to analyse and calculate span between max and min, time span etc.). You can also customize the grid of the graph easily. The **Data** tab allows for a quick reading of all the data, statistics such as max, min and average and the profile analysis with the result according to expected values. You can also export data to Excel or other format file.



Printed Report

TS Manager lets you print **complete reports of your processes**, with header image of your company and all the useful data to track the mission. You can choose to print graph, data table. Reports are printed according to regulations and can be signed on each page by the validator or the operator. Multi graph reports can be created thanks to the Group function: select all the missions you want to include in a new group and TS Manager will show all curves and data into a single graph and table. Sections can be generated to highlight different phases of the process and analysis are made on each section. Finding a mission is extremely easy thanks to a large set of filters. Quickly scroll through all the data acquired (date, time, temperature and pressure, eventually), look at the mission's statistics, like number of acquisitions, duration, maximum, minimum and average values for temperature and pressure. Export all the data, not only the acquisitions, but also all mission's details, to an Excel file. Analyse the data acquired using the chosen profile or select other profiles from the drop-down list. Add comments: create custom comments and load them automatically, to save time and create quick reports.

Report generated with					
TS MANAGER					
Statistiche Globali Da 07/05/14 12:30:00 A 07/05/14 12:36:00					
Min	13.44	07/05/2014 12:30:00	1501000013	FD	147.20
Max	141.36	07/05/2014 12:30:00	1501000013	FD	136.70
Med	116.85		PressureDak 1501000013	FD	139.47
Min med	113.69	1501004060			
Max med	139.28	1501002011			
Delta	108.92				
Max - med	24.51				
Med - min	43.41				
Delta max	21.49	07/05/14 12:31:44			
Min press.	1.04	07/05/2014 12:30:12	1501000013		
Max press.	3.74	07/05/2014 12:30:00	1501000013		
Med press.	2.12				

Report generated with					
TS MANAGER					
Statistiche Globali Da 07/05/14 12:12:00 A 07/05/14 14:00:13 Durata 01:48:08					
Sensore	1501004331	07/05/14 12:12:03 °C			
StatoDak	1501004063	07/05/14 12:12:35 °C			
StatoDak	1501000013	07/05/14 12:13:11 °C			
PressureDak	1501000013	07/05/14 12:13:11 Bar			
Statistiche Livelli Da 07/05/14 12:54:24 A 07/05/14 13:37:11 Durata 01:02:47					
Sensore	1501004331	07/05/14 12:12:03 °C			
StatoDak	1501004063	07/05/14 12:12:35 °C			
StatoDak	1501000013	07/05/14 12:13:11 °C			
PressureDak	1501000013	07/05/14 12:13:11 Bar			
Statistiche Ingrandimento Da 07/05/14 12:33:48 A 07/05/14 13:47:33 Durata 01:13:45					
Sensore	1501004331	07/05/14 12:12:03 °C			
StatoDak	1501004063	07/05/14 12:12:35 °C			
StatoDak	1501000013	07/05/14 12:13:11 °C			
PressureDak	1501000013	07/05/14 12:13:11 Bar			