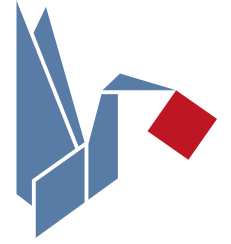


tecnosoft
WE DELIVER DATA



PHARMACEUTICAL, MEDICAL, HEALTHCARE



VALIDATION AND
PROCESS MONITORING





We deliver data

TECNOSOFT, was founded in 1989, as a research and development company specialized in technical-scientific fields, acquisition systems data and solutions for many different sectors including pharmaceutical, medical, healthcare and food.

TECNOSOFT collaborates with Ortho Clinical Diagnostics and Becton Dickinson in medical field and has developed solutions ad hoc for these and other successful companies.

30 years of experience have helped us develop an extensive knowledge of the problems related to medical aspects during the design of solutions and analysis of data of various fields, cold chain monitoring, validation of

sterilization. Thanks to its flexibility and its continuous updating Tecnosoft manages to grasp quickly user needs and turn them into new systems or existing solutions updates, as well as being able to customize them according to different needs.

TECNOSOFT's Advisory Team is capable to guide the customer in the choice of the right solution for every application, in addition to provide a full service such as short and long term rentals and assistance after-sales.

Since 2002 TECNOSOFT has implemented an ISO first certified quality system 9001: 2000 and now 9001: 2015, passing through the 9001: 2008.

Regulatory Compatibility

TECNOSOFT systems comply with industry standards and international guidelines

ISO 17665	Sterilization of healthcare products and routine checks of sterilization processes for medical devices
ISO 13060	Small Steam Sterilizers - Manufacturers
ISO 15883	Washer disinfectant - General requirements, conditions, definitions and tests
UNI EN 285	Sterilization - Steam sterilizers - Large sterilizers
FDA 21 CFR Part 11	US FDA Regulation for Electronic Registration Systems
GAMP5	Guidelines for good automated production procedures
Annex 11	European Regulation for Electronic Registration Systems

Fields of application for process monitoring and validation of equipments

The range of TECNOSOFT temperature, pressure and humidity Data Loggers is suitable for multiple applications.

Healthcare / Medical and Pharmaceutical field









- instrument washer
- steam sterilizers
- freeze dryers
- refrigerators, freezers, ultra freezers, cold rooms
- laboratories
- mapping and validation for autoclave
- hydrogen peroxide autoclaves
- monitoring of units and samples of plasma
- incubators

Their design, the AISI316L stainless steel material and the IP68 degree of protection make them extremely versatile.



Temperature, Pressure, Humidity: the Data Loggers

All data loggers are supplied with Accredia traceable calibration certificate and the battery is user replaceable.

	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
\emptyset	20 mm	20 mm	35 mm	35 mm	30 mm	18 mm	18 mm
Probe	Rigid Flexible Bendable	Rigid Flexible Bendable	Radial rigid	-	-	-	-
Battery autonomy							

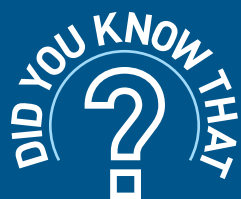


Maximum data logger range*: $-80^{\circ}\text{C} \div +140^{\circ}\text{C}$

Maximum probe range*: $-196^{\circ}\text{C} \div +500^{\circ}\text{C}$

Maximum accuracy: $\pm 0,1^{\circ}\text{C}$, ± 15 mbar (PressureDisk), $\pm 0,0003$ mbar (Pirani), $\pm 1,8\%$ (RHTemp)

* check the range actually covered by each data logger and probe, as well as the technical data of each device, on the website



What does validation mean?

Validation is a systematic and planned Quality process.

- The system or product or process must meet certain requirements
- It must comply with the law, regulations reference and policy business
- It must operate as we expect during its entire life cycle
- At the end of the life cycle all data related to the system or product or process must be carefully stored

We take into consideration the validation of autoclaves that use the most used sterilizing agent: steam.

Depending on the microorganism you want to break down you can set the autoclave to maintain different temperatures for a defined period. Sterilization is, in fact, a process based on temperature and on time. In order to raise the temperature it's necessary using the pressure and, for this reason, the parameters to be registered during a validation are temperature and pressure.

Although the regulatory demands for the validation may vary from country to country, there are some common aspects such as

the use of multiple temperature probes at the same time (the number depends on the capacity of the autoclave).

A validation system does more than just deliver the data recorded by the probes: time, temperature and pressure. There are a lot of other parameters of interest, such as lethality (F0, A0 etc.), the uniformity of the autoclave (the differences recorded between the sensors inside it), the stability time (the time it takes to reach one given temperature in all points of the autoclave), the theoretical temperature calculated by pressure in saturated steam (a further check taking advantage of the unique correspondence between pressure and temperature in an environment saturated with steam).

TECNOSOFT TS Manager validation system allows you to generate complete reports with all the parameters necessary for your validation.

TS Manager

TS Manager is the advanced validation software for autoclaves, developed according to 21 CFR Part 11 and GAMP guidelines.

Software features

- Data encryption for security against tampering
- Multi-level access (guest, standard, advanced, administrator) through login and password
- Client / server installation equipments and shared database
- Database of Clients and Tools for activities validation
- Audit Trail
- Wide choice of analyzes and statistics: Lethality (F0, A0, PU), Vacuum Leak Test, Stability, Maximum and Minimum Thresholds, Averages, Pressure Theoretical Temperature in Saturated Steam Vapor

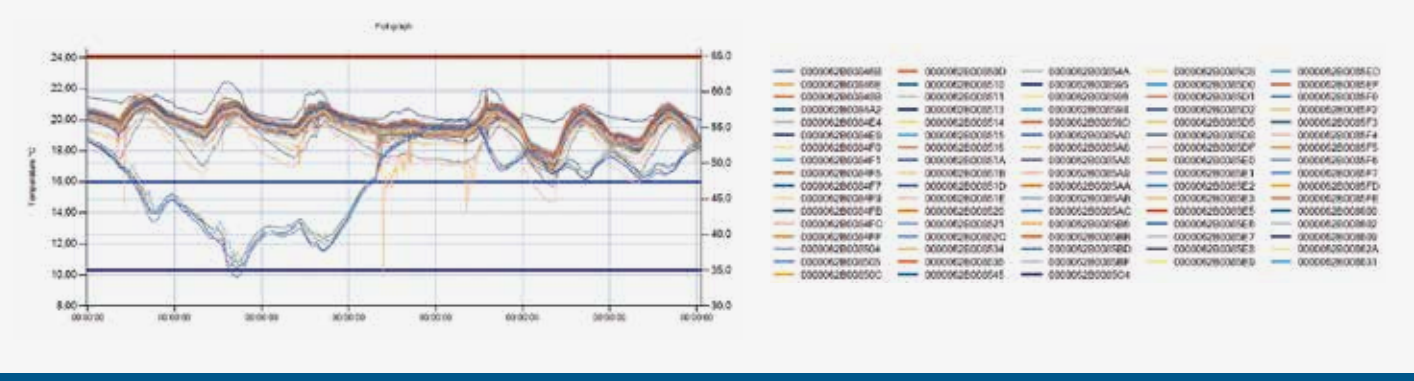
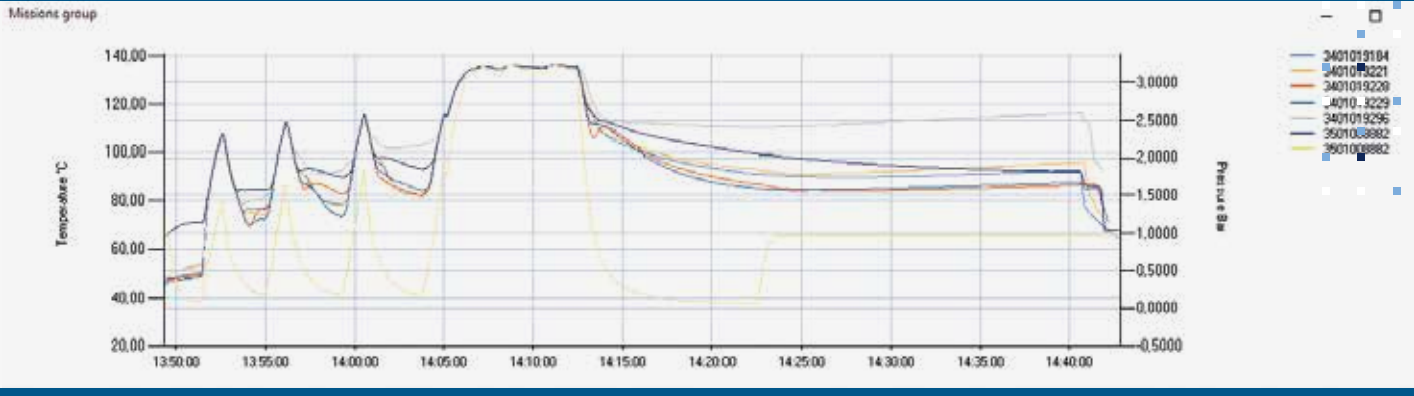
- Possibility of pre and post mission comments that can be save and edit
- Graph, with zoom, and Synchronized data table
- Multi chart with the possibility of sectioning it for separate analysis
- Customizable reports in every detail
- Export of data and reports to Excel
- Multilingual

We can provide IQ / OQ / PQ protocols on request. You can request a complete Validation KIT with devices and accessories

Accessories

- DiskInterface HS, PC connection base for programming and data reading
- Universal Multybay, multiple connection base, allows you to connect up to 5 data loggers
- Universal opening tool for battery change

Customizable reporting and advanced analysis for professional validation and mapping

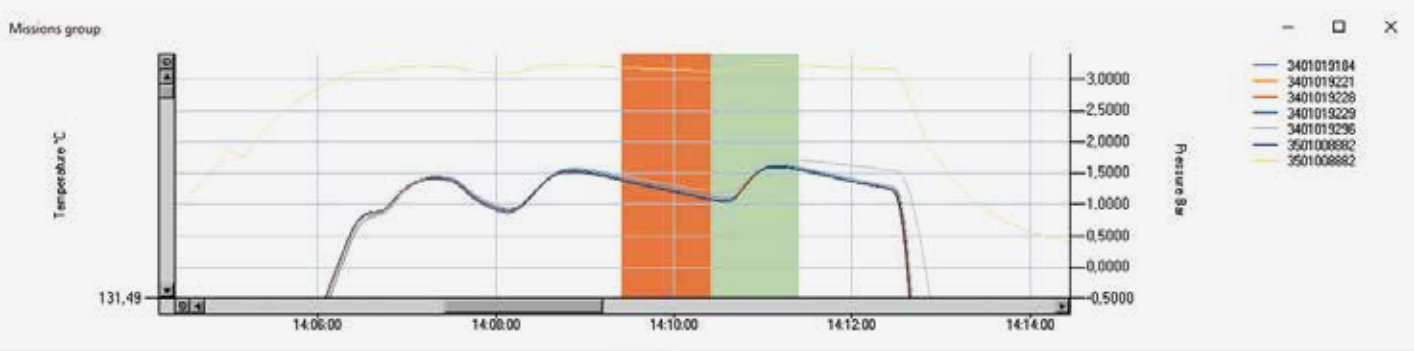


Statistics extra Global

Min °C	10,22	15/10/20 09:30:00	0000062B00850C
Max °C	22,43	13/10/20 14:00:00	0000062B008595
Avg °C	19,63		
Min avg °C	18,17	0000062B00864B	
Max avg °C	20,64	0000062B008595	
Delta Max-Min °C	12,21		
Max-Avg °C	2,80		
Avg-Min °C	9,41		
Delta Max °C	9,90	15/10/20 09:30:00	
Delta Min °C	0,00	19/10/20 00:00:00	
Min %RH	34,0	13/10/20 17:00:00	1000062B00203C
Max %RH	56,4	16/10/20 08:00:00	1000062B007072
Avg %RH	47,5		
Delta %RH	22,4		

Statistics extra Markers

Min °C	16,01	17/10/20 02:15:00	0000062B00864B
Max °C	22,43	13/10/20 14:00:00	0000062B008595
Avg °C	19,63		
Min avg °C	18,34	0000062B00864B	
Max avg °C	20,64	0000062B008595	
Delta Max-Min °C	6,42		
Max-Avg °C	2,80		
Avg-Min °C	3,62		
Delta Max °C			
Delta Min °C			
Min %RH	35,2	13/10/20 19:00:00	1000062B00203C
Max %RH	56,4	16/10/20 08:00:00	1000062B007072
Avg %RH	47,6		
Delta %RH	21,2		



What TECNOSOFT offers

Calibration and ISO-certificates



Maintenance and battery change in our laboratories



Technical assistance



Rental services with certified loggers



Personalization and extra calibration points



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