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ESIS
Industrial Electronics

Tecnosoft Validation &
Monitoring Solutions

TECNO Soft

# TS MANAGER

**Validation system for autoclave, compatible with FDA 21 CFR Part 11 regulations**

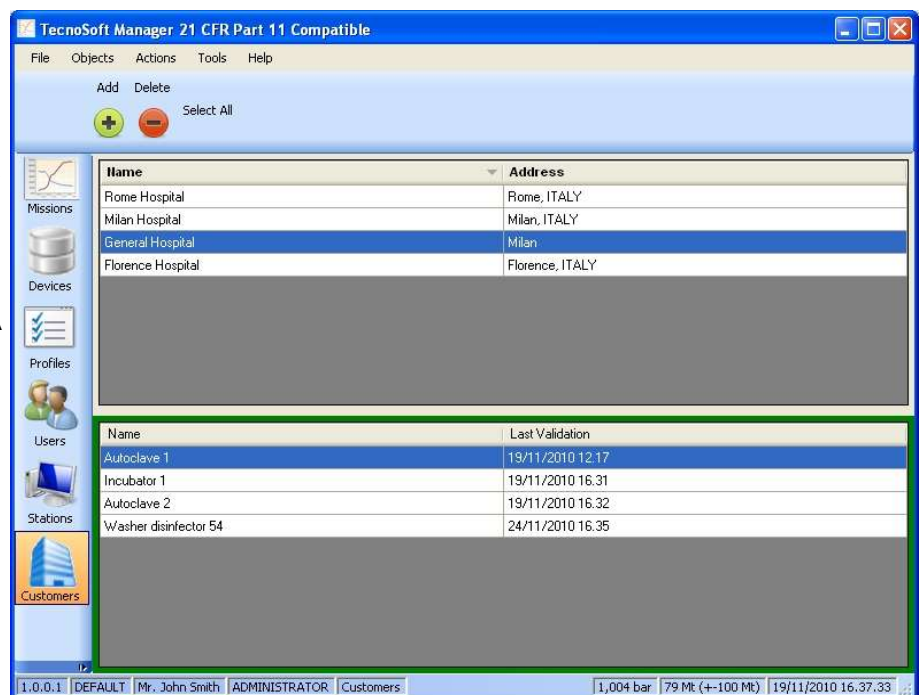## A Complete System for Thermal Validation

The TS Manager is a complete solution developed by Tecnosoft for all who need to monitor temperature in autoclaves, pasteurisers and in general high temperature processes and want to validate the process itself. It is based on the software with the same name, TS Manager, which is compatible with FDA 21 CFR Part 11 regulations, and all of high temperature Tecnosoft devices, along with the PressureDisk for **temperature and pressure** **monitoring**. All of them can work **up to 140°C** and resist at least **up to 6 bar** of pressure and can be used to map the autoclave and check if it is working well. All devices are made of food grade materials and are submersible, so that they can be used easily also in the food industry. With the TS Manager system it is possible to **validate equipment and processes** by professional validators.

## The Software

The TS Manager software has been developed with two main ideas: being **21 CFR Part 11 compatible** and being a "must-have" **resource for all validators** of autoclaves, incubators, pasteurisers and general equipment in the healthcare and food industry. So, it has all the features requested by the FDA regulations and other features that let the user manage all his/her validation for the different Customers.

Its intuitive interface 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.



## Process Analysis

### Setup Loggers

Starting a monitoring mission is quick and simple: put the logger in the DiskInterface already connected via USB and just press *Start*. The software will automatically recognize the type of logger connected and will show its status. Proceed and choose the profile to use to analyse your data. Profiles are set of parameters such as acquisition rate, start delay, kind of analysis (F0, Overkilling, PU etc.). Here you can assign also a Customer and an Instrument you are going to validate (autoclave, pasteuriser etc.). In the next step the logger will be programmed and you can assign also the use you are currently making of it (validation, test, production control etc.).

### Data Analysis

TS Manager offers you 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, user 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 portion 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, like F0 calculation and result according to expected values. You can also export data to Excel format file.
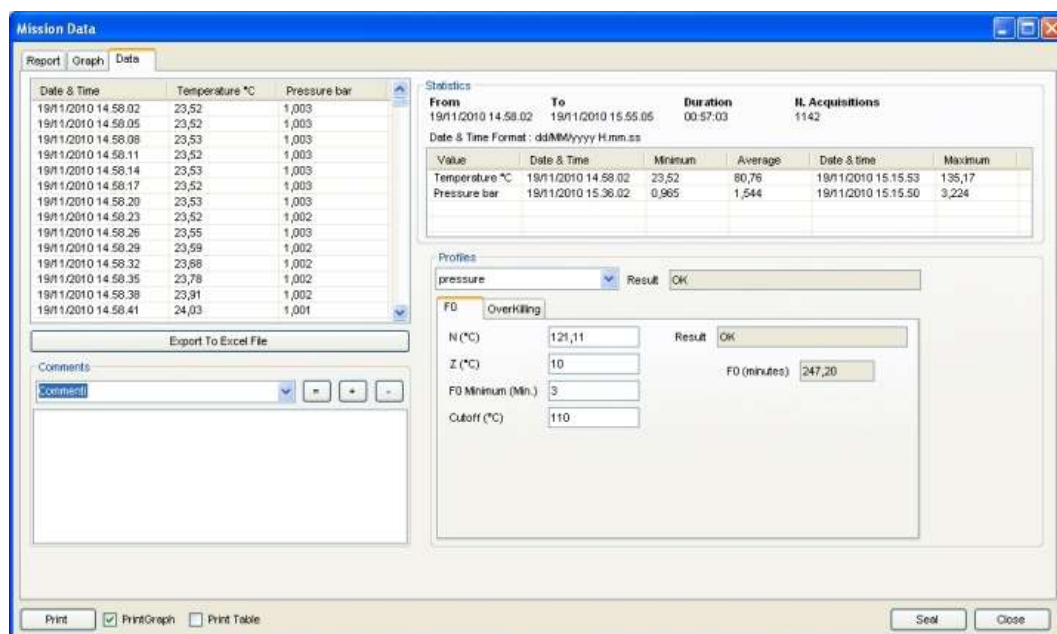
### Printed Report

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 user.

Set vertical and horizontal markers for your analysis and statistics, zoom in the graph in the most important phases of the current process, customize the grid according to your needs. You have plenty of options in the graph tab and all are user-friendly and quick to set. The **Seal** function is used to close an analysis and avoid possible further modifications to it.

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.
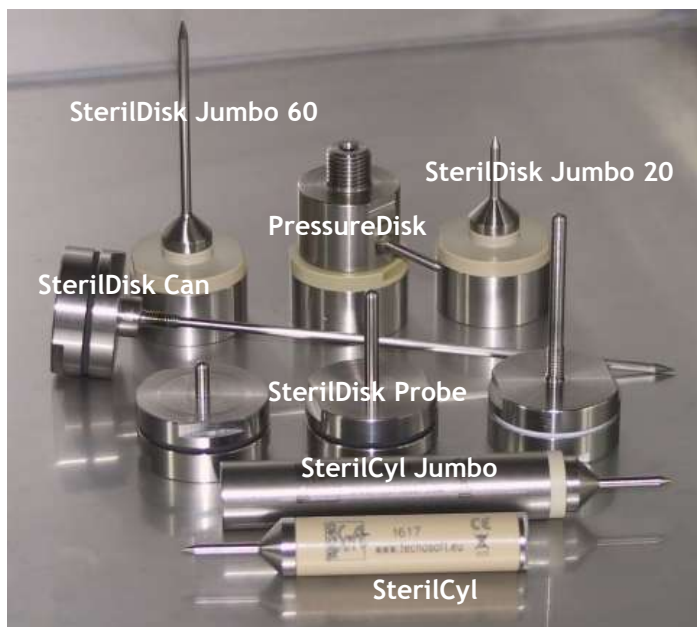


## Software Features

| Operating Systems | Windows XP, Vista, 7 (32 e 64 bit) |
|---|---|
| Data management | Database SQL **client/server** installation or stand-alone, data saved per mission (start and stop of acquisitions); available archives: mission templates (**profiles**), missions, **customers and instruments** (for validators), users (with **login, password, permissions** and validity period), stations (PCs where the software is installed), devices (list of all devices connected and used for validation), **activity log** (registry with all the activities of the software, with who's done what information); **filters** on: Customers, Instruments, date of mission start, user/station which started/stopped the mission, profile on analysis used at mission start, device used for validation/monitoring |
| Data presentation | **HTML report** (exportable), **graph with zoom** and vertical/horizontal markers, table with **statistics** (max, min, average) and analysis (**F0, PU, overkilling**), export into **Excel**, **report printing** |
| Compliant with | **FDA 21 CFR Part 11** compatible: users have login, password and permissions, data cannot be edited, devices cannot be tampered, database hacks checking feature for auditors, Audit option, Sealing feature for analysis on data (avoid further changes), all actions recorded in the log, printed reports |
| Languages | English, Italian |

# The devices

The TS Manager systems can be used with the PressureDisk and all devices for high temperature from Tecnosoft. All the loggers are made in food grade material (stainless steel AISI 316L and PEEK), are IP68, resist up to 140°C and 5 bar.  Each device has been studied for specific applications and therefore has different feature. Choose the logger that best fit your application, either being it a pharmaceutical/medical or a food application. The system is provided in an elegant case with all devices, cables, accessories, software and **calibration certificates**.



## Applications

The are devices of different size, shape and performances available for any kind of application.

| Helthcare, Medical, Pharmaceutical | Food & Beverages |
|---|---|
| Autolcave | Pasteuriser - Autoclaves |
| Steam sterilisation | Retorts |
| Incubators | Cooker/Cooler |
| Stability Chambers | Freezer |
| Stockhouse/Warehouse | Smoke house |
| Cold Storage | Fridge / Fridge Cell |



## Fastening System

There probes can be fitted to different type of packages. Flexible probes available too

| Healthcare, Medical, Pharmaceutical | Food & Beverages |
|---|---|
| Bottles | Cans |
| Pouches | Bottles |
| Tubes & Syringes | Pouches |
| Ampoules | Jars |
| Vials | Trays |

# Technical Data

**Material**: Stainless steel AISI316L, Peek (food grade) - **Acquisition rate**: From 1 acquisition every second up
**Temperature range**: Pasteur- 0°C ÷ 100°C; Steril- 0°C ÷ 140°C (other ranges available)
**Temperature resolution**: 0,02°C - **Temperature accuracy**: +/-0,2°C
**Pressure range (PressureDisk)**: 10 mbar ÷ 5000 mbar abs. - **Pressure resolution**: 2 mbar - **Pressure accuracy**: 15 mbar
**Accessories**: DiskInterface, adapter (for all but PastuerDisk/SterilDisk and PasteurDisk/SterilDisk Can)

| | | Dimensions Diameter X Height (mm) | Probe size D X H (mm) | N. acquisitions | Battery life |
|---|---|---|---|---|---|
|  | **PasteurDisk SterilDisk** | 36 X 17 | - | 15000 | 2 years with standard use – **user replaceable** |
|  | **PasteurDisk SterilDisk Probe** | 36 X 17 | 4 X 10, 30, 50 | 15000 | 2 years with standard use – **user replaceable** |
|  | **PasteurDisk SterilDisk Can** | 36 X 17 | 3 X 82, 117, 135 | 15000 | 2 years with standard use – **user replaceable** |
|  | **PasteurCyl SterilCyl** | 15 X 70 | 3 X 20, 60, 125 | 15000 | 2 years with standard use |
|  | **PasteurDisk SterilDisk Jumbo** | 35 X 35 | 3 X 20, 60, 125 | 120000 | 4 years with standard use – **user replaceable** |
|  | **PasteurCyl SterilCyl Jumbo** | 18 X 100 | 3 X 20, 60, 125 | 120000 | 4 years with standard use – **user replaceable** |
|  | **PressureDisk** | 35 X 54,22 | 3 X 23 | 60576 | 2 years with standard use – **user replaceable** |

# Loggers Comparison

**Explanation**: stars (*) are given according to the performance of the logger for that specific feature.

| | Dimensions | Battery Life | User replaceable | Response Time | Applications |
|---|---|---|---|---|---|
| **PasteurDisk/SterilDisk** | *** | * | Yes | * | Limited height in conveyer belt; small packaging |
| **PasteurDisk/SterilDisk Probe** | ***-* | * | Yes | ** | Higher response time than PasteurDisk and SterilDisk |
| **PasteurDisk/SterilDisk Can** | ***-** | * | Yes | *** | For cans of all size, always reach the cold spot, easy fitting |
| **PasteurCyl/SterilCyl** | **** | * | Yes | *** | Limited height or reduced space; small packaging; fast response time |
| **PasteurDisk/SterilDisk Jumbo** | ** | *** | Yes | *** | For intense use, exceptional battery life and memory |
| **PasteurCyl/SterilCyl Jumbo** | * | *** | Yes | *** | For intense use, exceptional battery life and memory |
| **PressureDisk** | ** | ** | Yes | *** | Choose this if you need to monitor pressure too |

All loggers are provided with a **calibration certificate** SIT (NIST equivalent) traceable. Calibration is made on different points of temperature and temperature / pressure for the PressureDisk.
If you need special calibration points, ask for availability.

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