Testo
Application example

Be sure. testo

Highly efficient cGxP validation of the sterilization process of Pharmaceuticals and other industries with the testo 190 CFR data logger system.

In order to ensure and meet cGxP compliant manufacturing processes companies must ensure 21 CFR Part 11/Annex 11 compliance and security throughout the sterilization process within autoclaves. These critical processes must be validated at regular intervals as well as for minimum and maximum loads within the autoclave. For this purpose, wired thermocouples and wireless systems are in use today for measuring temperature, pressure, and lethality within autoclave systems. When using sterilization systems, Excel spreadsheets with complex calculations are frequently used as standard-compliant documentation.

In order to alleviate validation representatives from compiling large swaths of data and making labor intensive calculations, testo developed the testo 190 CFR data logger system. The testo 190 CFR data logger system is the intelligent solution for the cGxP monitoring and documentation of temperature, pressure, and lethality in sterilization processes.
The smart all-in-one solution, the testo 190 CFR data logger comprises of robust hardware and intuitive software, which enables you to monitor sterilization processes more efficiently while sustainably optimizing each process. Testo also offers exceptional service to help or guide users to develop efficient processes.. This means you reliably adhere to government regulatory site standards while saving time and money.

Testo North America
www.testo.com
800-227-0729
info@testo.com

The Challenge

The objective of sterilization is to kill off microbial life that may be present on any load. Loads that have undergone a full steam sterilization cycle are then considered to be sterile and can then be used within a specific regulated environment without the fear of introducing outside microbial life. Regulated environments can range from laboratories, hospitals, operating rooms, food facilities, and the pharmaceutical industry. Each regulated environment will have different goods or materials that will need to be sterilized. Different materials and load sizes can be sterilized at different lengths of time in parallel with biological indicators in order show complete lethality. In order to achieve complete compliance there are several cost and time-consuming steps necessary to perform the validation of the sterilization process:

1. **Positioning measurement technology**
   In order to obtain reliable measurement values within the steam sterilizer, the temperature and pressure sensors have to be placed and positioned in the steam sterilization machine or product using autoclavable adhesive tape or other aids. The correct set-up in an average steam sterilizer can take several hours depending on size.

2. **Evaluation of the measurement values**
   Several pages of recorded measurement values and data is expected with this type of measurement, representing a considerable challenge in terms of time for the validation representative or member evaluating the measurement data results. The measurement data needs to be completely checked and prepared with visual tables and graphs which is almost impossible to process quickly using standard software programs.

3. **Calculations**
   In order to determine the success of the sterilization validation measurement, the lethality, or F_0 Value must be calculated. The F_0 value or lethality is calculated by time in minutes at which the temperature of or above 121°C is delivered by the process to the product in its final container with reference to microbial life possessing a Z-Value of 10. In sterilization processes, the quality of the saturated steam is crucial for complete lethality. The calculation of the lethality parameter is currently carried out using supporting tables or Excel spreadsheets, which can introduce the risk of an input or operator error, and on the other hand is very time-consuming.

4. **Placement Image Documentation**
   In validation, the data logger placements have to be documented with images or pictures. The image documenting is necessary in order to be able to reproduce the exact positioning of the temperature sensors during the sterilization measurement. Documenting image placements of loggers is crucial as in some cases there might be 40 or more measurement points which can take several hours to compile documentation of those placements.

The Solution

Data loggers

21 CFR Part 11 Software

Multifunction case

The testo 190 CFR data logger system allows a highly efficient validation of the sterilization of pharmaceutical products or any type of sterilization application within other industries. The system consists of robust, durable and reliable **CFR data loggers** in five different models consisting of four temperature and one pressure model; **a multifunction case**, which serves the lightning fast programming and readout of the loggers as well as their safe storage and transport; and the unique **testo 190 CFR software** which enables full, compliant, and audit-relevant documentation with the click of a mouse.

In the development of the 21 CFR Part 11-compliant software, special attention was paid to intuitive operation and regulatory requirements. The user is guided safely, step by step through the qualification process, while receiving warnings at critical points. The software is therefore equally suitable for experts and beginners as well as being fully compliant with regulatory agencies.

Using the CFR software and multifunction case, up to 8 data loggers, which can be time or temperature controlled, can be programmed or readout at a time via a connection cable between the case and user's computer.

In the context of the data analysis of the sterilization measurements, the calculations for the holding phases are automatically carried out and checked against your defined acceptance criteria. In addition, the software enables fast and easy creation of the logger placement image documentation. The best part about the complete testo 190 CFR data logger system is that there is no effort for assembling all the documentation as it can be simply assembled with one click of the mouse.

Overview of Advantages

- Large measurement data memory
- Fast and reliable overview of the measurement results
- Less effort and lower error potential
- No data export to other systems needed
- Compliant with cGxP and 21 CFR Part 11
- 1-click report
- Integration of up to 254 measurement points per validation process into the software possible

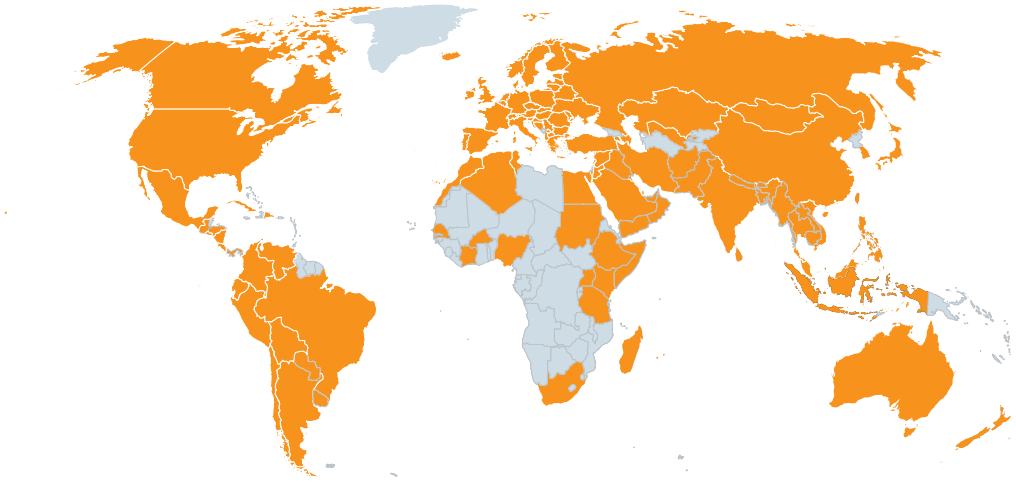
Be sure. testo

Testo:
High-tech from the Black Forest.

Testo is a world leader in the design, development, and manufacture of innovative products and services for environmental and industrial measurement. For more than 60 years, leading companies in the life sciences industries have relied on Testo to help protect their products.

Testo's first product was a simple electronic thermometer. Today, the product line has expanded to include a large variety of critical measuring instruments, such as data loggers, air velocity meters, humidity and dew point meters, sound, pressure, and light meters.

With over 2,700 employees in 33 offices worldwide, Testo understands local requirements and culture. Testo currently has hundreds of thousands of data loggers in the market, storing over 17 billion data sets.



Testo Country Sales and Service Organizations

Testo North America
www.testo.com
800-227-0729
info@testo.com