

Be sure. **testo**



**Durable:** ✓  
**Intuitive:** ✓  
**Reliable:** ✓

Highly efficient validation of your sterilization and freeze-drying processes with the testo 190 CFR data logger system.

## Comprehensive support: Your validation with Testo.

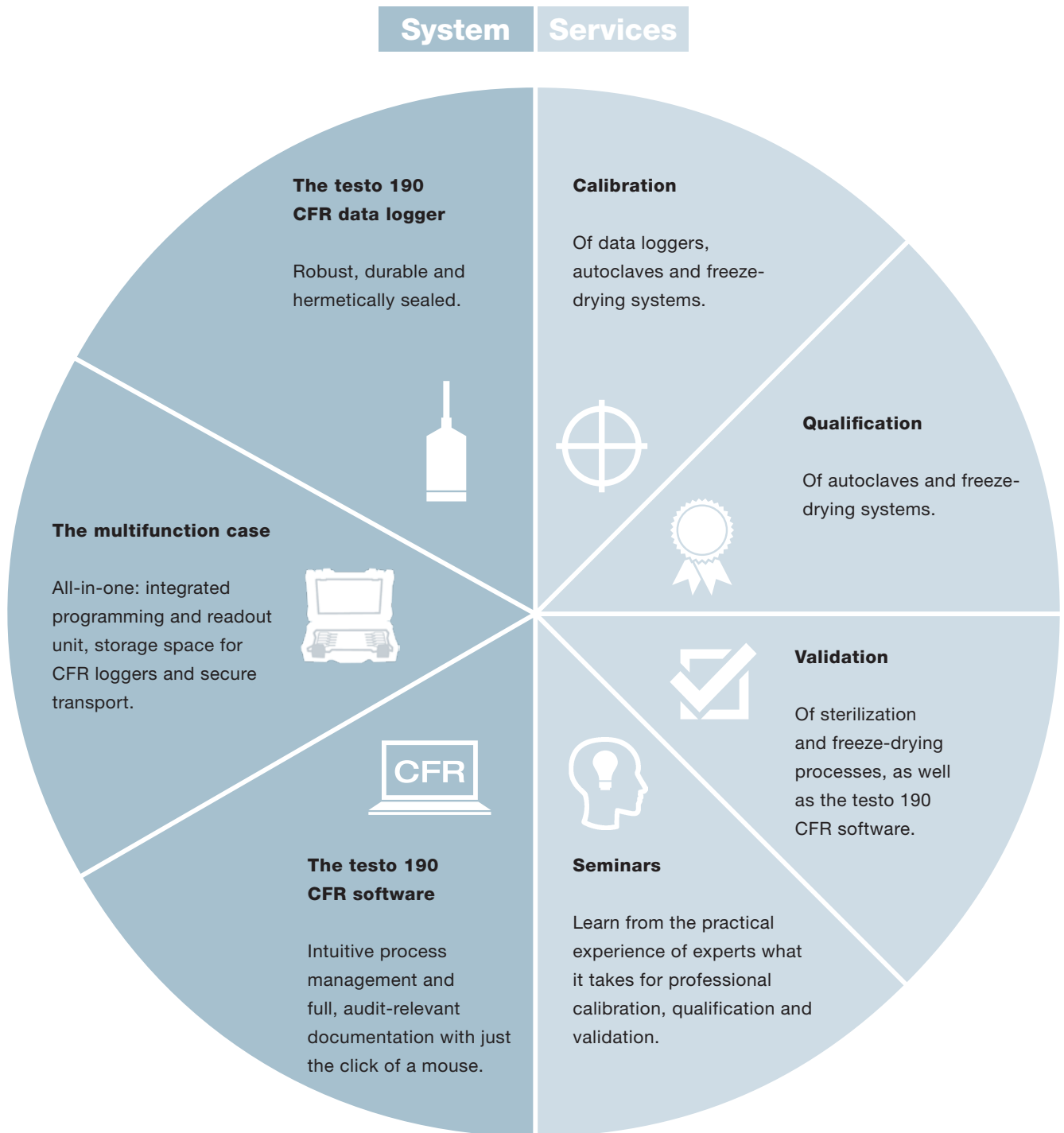
The validation of sterilization and freeze-drying processes is a key element of your quality assurance and shows the high level of safety of the products you make. With our testo 190 CFR data logger system, we support you according to your needs in terms of fulfilling all regulatory requirements in a highly efficient way.

Entrust your whole validation process to us and take advantage of a resource-friendly, full-service solution enabling you to reliably achieve your GMP compliance. Alternatively, we are happy to support you with individual services specially tailored to your needs, such as training courses, calibrations, qualifications and validations. In all respects, Testo is your reliable partner when it comes to meeting your individual requirements.





# Hardware, software, service: Your building blocks for efficient validation.



# Innovation in the smallest space: The advantages of the testo 190.

The testo 190 CFR data loggers for temperature and pressure are available in five different versions. Hermetically sealed measuring technology in a separate stainless steel housing means their reliability and maximum robustness are impressive.

The battery can be changed quickly and safely without any tools or lubricants at all. And you will also have no problem meeting the "10% failure rate" acceptance criterion with the testo 190.

## Versatile probes

Measurement probes are available in different serial designs.

## Easy securing option

Practical solution for attaching the retaining clamps.

## Robust stainless steel

The measuring technology is fitted into a hermetically sealed stainless steel housing.

## Reliably tight

The data loggers remain 100% tight even after the batteries are changed.

## Resilient plastic

The battery housing is coated in high-temperature-resistant polyether ether ketone (PEEK).

## Flexible height

Depending on the measuring task, you can adapt the height of the data loggers via the batteries which are available in two sizes.



## Unique design

The battery and the measuring technology are contained in two separate housings.

## Fast battery change

Thanks to the innovative design, the batteries can be safely changed in just a few seconds without any tools.



## Practical accessories



### Small battery

With a service life of 250 operating hours and compact dimensions ideally suited to confined applications.



### Probe holder (puck)

The probe holder ensures precise measurement of the surface temperature (plate temperature) in a freeze-drying system.



### Retaining clamp

In combination with cable ties, the retaining clamp enables easy and safe securing of the logger, without any residues being left behind.

## At a glance: A comparison of the data loggers.



CFR data loggers	testo 190-T1	testo 190-T2	testo 190-T3	testo 190-T4	testo 190-P1
Measurement parameter / probe type	Temperature (Pt1000)				Pressure (piezoresistive sensor)
Measuring range	-50 to +140°C				1 mbar to 4 bar abs.
Accuracy	±0,2 °C (-50 to -40 °C) ±0,1 °C (-40 to +140 °C)				± 20 mbar
Resolution	0.01°C				1 mbar
Reading memory	60,000 readings			30,000 per channel	60,000 readings
Measuring cycle	1 s to 24 h				
Storage temperature	-20 to +50°C				
Dimensions					
Logger with small battery	20 x 40 mm (Ø x H)		20 x 45 mm (Ø x H)	20 x 53 mm (Ø x H)	22 x 64 mm (Ø x H)
Logger with large battery	20 x 59 mm (Ø x H)		20 x 63 mm (Ø x H)	20 x 72 mm (Ø x H)	22 x 83 mm (Ø x H)
Probe shaft	3 x 25 mm	3 x 115 mm	1.5 x 775 mm		-
Probe shaft tip	-		3 x 25 mm		-
<b>Battery large (standard)</b>					
Battery type	½ AA lithium				
Service life	2,500 operating hours (measuring cycle 10 seconds at 121°C)				
Application range	-50 to +140°C				
<b>Battery small (option)</b>					
Battery type	2 x button cell lithium				
Service life	250 operating hours (measuring cycle 10 seconds at 121°C)				
Application range	-20 to +140°C				

# The multifunction case: Configuration, readout, transport.

Flexible to use, practical to handle and especially robust – the transport case for the testo 190 CFR data loggers has many impressive features. In addition to providing secure

storage, they also ensure fast configuration and readout of the loggers with the testo 190 CFR software.



#### **More efficient**

The case enables up to eight testo 190 data loggers to be wirelessly configured and read out simultaneously.

#### **More practical**

The programming and readout unit is permanently installed in the case. So you do not need to switch between transport appliance and programming / readout unit.

#### **More secure**

The data loggers are reliably protected against damage in the solid case.



## Surprisingly easy: The testo 190 CFR software.

The 21 CFR Part 11-compliant testo 190 CFR software provides you with effective support in your validation and qualification tasks. From fast simultaneous configuration and readout of up to eight data loggers, via comprehensive data analysis to easy, audit-relevant reporting.

The clear software structure guides you intuitively through the process step by step and helps you at critical points in the input process through warnings. The range of functions was deliberately restricted to the features which you really need for successful validation.

**You will be impressed by these advantages:**

- ✓ **Full, audit-relevant documentation with just the click of a mouse (1-click report).**
- ✓ **Whether you are an expert or a novice: testo 190 CFR software provides every user with optimum support during the measuring process.**
- ✓ **Fast and reliable overview of the measurement results.**
- ✓ **No data export to other systems needed (e.g. to Excel).**
- ✓ **Readout of up to 254 loggers is possible in one validation process.**





## Tailor-made service: So you can concentrate on what's important.

You can rely on Testo's experience and expertise for all services relating to the validation of your sterilization and freeze-drying processes.

We implement your wishes and requirements in the areas of calibration, qualification, validation and GxP compliance according to needs and, at the same time, cost-sensitively. Additionally, our experts support you in the introduction, maintenance and optimization of your quality assurance and can provide the necessary manpower at peak times or for more comprehensive projects. That saves you time and resources.

Determine the scope of our services yourself: whether for carrying out full validation or for calibrations and training – you can rely on individual support for your requirements. Together with you, we will find appropriate solutions.





## Validation of processes and software

### Individual validation of your steam sterilization and freeze-drying processes

- Creation of the validation concept and, on request, taking on the entire project coordination
- Validation of sterilization and freeze-drying processes, including carrying out all measurements and creating risk analyses

### Validation of the testo 190 CFR software

- Individual software validation according to requirements which is compliant with 21 CFR Part 11 and Annex 11 (EU-GMP guideline)
- On request, you are provided with the validation templates for carrying out the software validation yourself
- Customer-specific development or joint design of sterilization processes

## Qualification

### GxP-compliant qualification of your systems

- Fulfilling GxP compliance through risk-based qualification of your steam sterilization and freeze-drying systems
- Qualification support and creation of documents across all qualification phases
- Carrying out qualification measurements (e.g. mappings, distribution measurements and challenge tests)

## Calibration

### Calibration of the testo 190 data loggers in accredited laboratories

- Reliable measurement results thanks to highly accurate calibration of your data loggers – traceable to national or international standards
- Depending on your individual needs, you get accredited (e.g. DAkkS) or ISO calibrations
- All calibration certificates are available to you in PDF format in our calibration system

### Calibration of your stationary systems

- We carry out flexible calibration which is independent of the manufacturer, e.g. of your autoclaves and freeze-drying systems, conveniently at your business premises – allowing your systems to stay permanently available

## Seminars and training

### Take advantage of our expertise in the field of steam sterilization and validation

- Find out what the correctly executed validation of steam sterilization processes is all about
- Get an overview of the regulatory and normative requirements
- Implement the theory right away in practical workshops

# Ordering information.

testo 190 system components	Order no.
<b>Data loggers</b>	
<b>testo 190-T1</b> , CFR temperature data logger, including large battery and adapter for testo 190 programming and readout unit.	0572 1901
<b>testo 190-T2</b> , CFR temperature data logger, including large battery and adapter for testo 190 programming and readout unit.	0572 1902
<b>testo 190-T3</b> , CFR temperature data logger, including battery large and adapter for testo 190 programming and readout unit.	0572 1903
<b>testo 190-T4</b> , CFR temperature data logger, including large battery, adapter for testo 190 programming and readout unit and thread extension.	0572 1904
<b>testo 190-P1</b> , CFR pressure data logger, including large battery.	0572 1900
<b>Software</b>	
<b>testo 190 CFR software</b> , 21 CFR Part 11-compliant software for configuration and readout of testo 190 CFR data loggers. System requirements: Windows 7 (32/64 bit), Windows 8, Windows 10.	0554 1901
<b>Case</b>	
<b>testo 190 small case</b> , case for transport, storage, configuration and readout of testo 190 CFR data loggers. Including USBcable and 1 programming and readout unit for a maximum of 8 data loggers. Dimensions: 340 x 265 x 60 mm.	0516 1901

Services offered by Testo Industrial Services	Order no.
On-site ISO calibration of autoclaves and freeze-drying systems (temperature)	0521 9231
On-site ISO calibration of autoclaves and freeze-drying systems (pressure)	0521 9232
On-site DAkkS calibration of autoclaves and freeze-drying systems (temperature)	0521 9235
On-site DAkkS calibration of autoclaves and freeze-drying systems (pressure)	0521 9236
ISO/DAkkS calibration of other measurement parameters (e.g. conductivity, time and lots more)	On request
Qualification of autoclaves and freeze-drying systems (including mappings)	0521 8200
Validation of sterilization and lyophilization processes	0521 9302
Validation of the testo 190 CFR software	0521 9723
Practical steam sterilization workshop	0522 1205



# testo 190 accessories.

testo 190 accessories	Order no.
testo 190 small battery, PEEK coated. For the power supply of all testo 190 models. Application range: -20 to +140°C.	0515 1900
testo 190 battery large, PEEK coated. For the power supply of all testo 190 models. Application range: -50 to +140°C.	0515 1901
testo 190 freeze-drying probe holder (puck) for more precise measurement of surface temperature with the testo 190-T3 and testo 190-T4.	0554 1907
Retaining clamps (5 off), to secure the loggers (testo 190-T1/-T2/-T3/-T4) in the application areas (e.g. in autoclaves).	0554 0297
Distance adapters short to secure the testo 190-T4 data logger in the programming and readout unit.	0554 0298
Distance adapters long to secure the testo 190-T1, testo 190-T2 and testo 190-T3 data loggers in the programming and readout unit.	0554 0299
ISO temperature calibration certificate (testo 190-T1/-T2/-T3/-T4), calibration points -50°C; 0°C; +90°C; +121°C; +140°C	0520 0141
DAkkS temperature calibration certificate (testo 190-T1/-T2/-T3/-T4), calibration points -50°C; 0°C; +90°C; +121°C; +140°C	0520 0281
ISO pressure calibration certificate (testo 190-P1), calibration points 200 / 1400 / 2600 / 3800 / 5000 mbar	0520 0025
DAkkS pressure calibration certificate (testo 190-P1), calibration points 200 / 800 / 1400 / 2000 / 2600 / 3200 / 3800 / 4400 / 5000 mbar	0520 0215



Small or large battery available



Freeze-drying probe holder (puck)



Retaining clamp



Distance adapters short / long





# Testo: High-tech from the Black Forest.



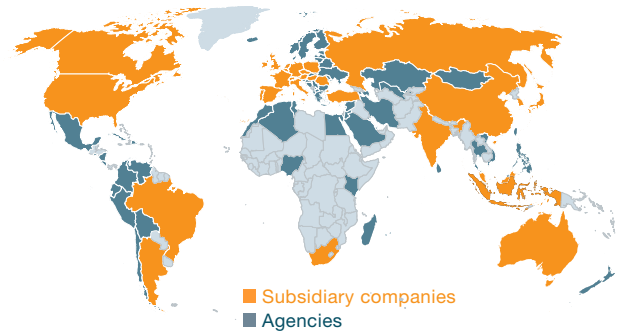
## With roots in the Black Forest.

For 60 years, Testo has stood for innovative measuring solutions made in Germany. As a world market leader in portable measuring technology, we help more than 650,000 customers to save both time and resources, to protect the environment and human health, and to improve the quality of goods and services. These measurement solutions are complemented by the quality assurance services of our subsidiary company Testo Industrial Services.

Their core services include calibration, qualification and validation, which are indispensable for the achievement of impeccable quality in the pharmaceutical industry and in GxP-regulated environments. Our services are as individual as your products: we support and accompany you in your tasks and projects for the fulfilment of GxP compliance – from conception to realization.

## At home all over the world.

Our headquarters are in Lenzkirch in the Black Forest. However, Testo has for many years been a constantly growing global concern, now represented on all continents by more than 33 subsidiary companies and over 80 distribution partners. Around 3,000 employees research, develop, produce and market for the company with passion and expertise all over the world.



Subject to change, including technical modifications.

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