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We measure it. **testo**

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# It's simple.

USB data logger testo 184. Easy temperature monitoring and uninterrupted quality documentation in the transportation of pharmaceuticals.

# Reliable monitoring of temperature, humidity, and shock.

The USB data logger testo 184 for pharmaceutical logistics.

Transport and storage of pharmaceuticals require maintenance of predefined temperature and humidity values. When those pre-set values go out of range they can cause changes in active drug ingredients.

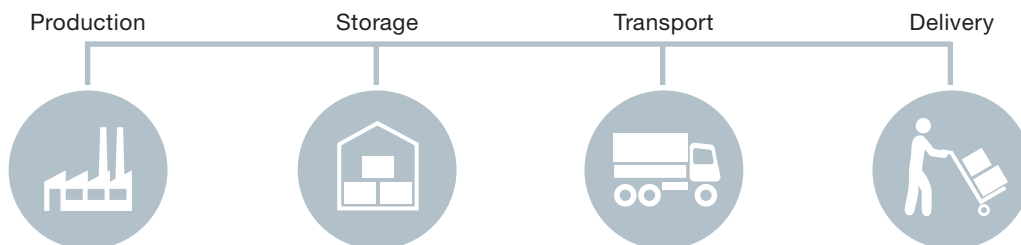
Biologicals contain proteins sensitive to ambient temperature changes; freezing can lower effectiveness and in worst cases can degrade antigens or form toxic products. Increased temperatures also promote degradation and/or bacterial growth conditions.

However, not only drugs and their active ingredients can be affected by temperature changes. Sub-freezing temperatures, temperature shocks, or fluctuations can cause hairline cracks in glass or plastic packaging. Such cracks lead to a loss of sterility, and high humidity can cause clumping or swelling of hygroscopic ingredients.

The testo 184 is a reliable tool to monitor temperature, humidity, and impact (shock value) in transport of drugs and deep-frozen plasma. At the destination point, the recipient can immediately find out if the transport conditions were within the specifications either by the display markings or the color of blinking LEDs. testo 184 allows for fast and easy retrieval of information on transport conditions by printing results on Testo NFC printer, via an Android Smartphone using the testo 184 App or plugging into the PC's USB port. The report PDF generated by stopping the logger is immediately available for reading, printing, or email.

The testo 184 is designed for high efficiency and ease of use. All you need to know about the logger's operation is enclosed on the logger acting as a thumb drive:

- Configuration file
- Acceptance test certificate (only testo 184 T1 – T4)
- Instruction manual
- PDF report of your recorded measurement data.





# Perfect for GDP, GMP. And you.




Testo 184 data loggers assure compliance with pharmaceutical guidelines and regulations.

At the next audit, you will be able to prove that the transport conditions are fully monitored according to your GDP or GMP rules.

### testo 184 features help you in your daily work:

- Low learning curve thanks to intuitive operation. Alarms are easily identified on the front side of the logger.
- Alarm settings are well-suited for pharmaceutical transport applications allowing multiple alarm settings and time-controlled cumulative excursion alarms.
- The MKT value calculation setting is preset in the Setup file.
- testo 184 enables compliance with 21 CFR Part 11 when used with testo ComSoft CFR software.
- Temperature data loggers testo 184 T1, T2, T3, and T4 come with acceptance test certificate according to DIN ISO 10204.
- testo 184 H1 and G1 have the ISO or NIST calibration option.

**Certificate** Data Logger testo 184 

**Allgemein / General / Général / General:**

Gerät / Module type / Modèle / Modelo: testo 184 T1  
 Serien-Nr. / Serial no. / No. de série / Número de serie: 43811103  
 Messbereich / Measuring range / Etendue de mesure / Rango de medición: -35.0 ... +70.0 °C  
 Zulässige Toleranz / Permissible tolerance / Tolerancia admise / Tolerancia permitida: ± 0.5 °C

**Sollwert / Reference / Référence / Referencia:**

Type	Certificate	Uncertainty(k=2)
Agilent34410A	SMQ143403238	0.1 Ohm

**Sensor / Sensor / Capteur / Capteur**

Type	Certificate	Accuracy @5.0°C
TT3-5KCs-80	5059Z 05/15	± 0.1 °C

**Elektronische Kalibrierung / Electronic calibration / Etalonnage électronique / Calibración electrónica**

No.	Reference(°C)	Reading(°C)	Deviation(°C)
1	-30.02	-29.89	0.14
2	-10.02	-10.01	0.01
3	5.01	4.98	-0.03
4	24.98	24.95	-0.03
5	69.97	69.97	0.00

**Systemunsicherheit / System uncertainty / L'incertitude du système / Incertidumbre system**

Sollwert / Reference / Référence / Referencia:	Zulässige Toleranz / Permissible tolerance / Tolerancia admise / Tolerancia permitida:	Unsicherheit / Uncertainty / Incertitude / Incertidumbre:
5.0 °C	± 0.5 °C	0.06 °C

This document has been created automatically and is valid without signature. Prüfer / Inspector / Verificateur / Verificador: 853 Datum / Date / Fecha: 2016-03-23

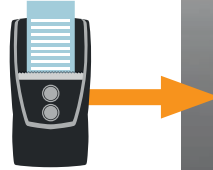
Temperature data loggers testo 184 T1, T2, T3, and T4 come with an acceptance test certificate according to DIN ISO 10204. Further traceable calibration certificates according to ISO 17025 or DAkkS are available on request.

# Numerous possibilities for reading out or printing PDF reports.



## NFC-printing

The report is automatically read and printed by NFC technology. Just hold the logger close to a NFC printer from Testo.



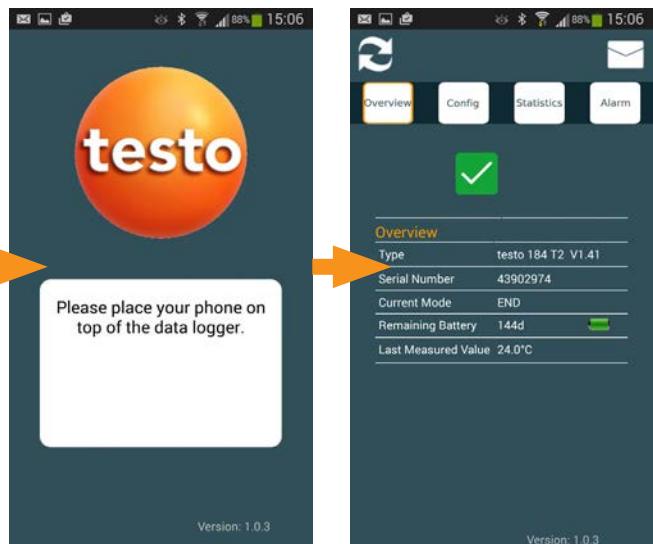
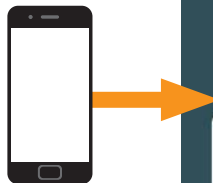
## USB Connectivity

As soon as you connect the logger to a computer by USB, the PDF report is automatically called up.



## Reading out

Near Field Communication (NFC) allows the reports to be read out by simply holding the data logger close to an Android smartphone with the testo 184 App. The PDF report is automatically called up, and can be read out and sent by e-mail.



# Plug and Play.

More advantages of the testo 184 data loggers [at a glance.](#)



### Clear alarm indication

A glance at the display or the LEDs is enough to know whether limit values have been violated during transport.



### Easiest operation

testo 184 is intuitively operated and can be used without special training or previous knowledge. The "Start" button begins data recording, "Stop" ends it.



### IT-secure

The testo 184 data loggers work securely without software installation or download, so that problems are triggered neither by the firewall nor the virus scanner of your IT department.



### Easiest configuration

A configuration file is stored in each testo 184, making the configuration of the data loggers child's play – no download, no installation, no user interface, and no additional costs.



# GxP, CFR, and ISO.

The most important standards for the transport of pharmaceuticals at a glance.

## GMP Guidelines

In a GxP-regulated environment, especially high demands are placed on quality management. Not only GMP or GLP, but also GDP (Good Distribution Practice) guidelines play an increasingly important part. The adherence to the regulations for the transport and storage of pharmaceutical raw materials, products, auxiliary substances, and intermediate products can be guaranteed without any problems with the help of the Testo data loggers.

## ISO 9001:2008

ISO 9001:2008 is the most significant international norm for quality management systems, and guarantees the framework conditions for a high level of quality-capability for products and processes. However, in connection with this, it is also indispensable to be fully informed of the professional quality assurance of the suppliers involved in the process. Testo AG, as an ISO 9001:2008-certified company, fully complies with these requirements, and ensures the adherence to the norms through internal audits as well as accredited external audits.

## FDA 21 CFR Part 11

The FDA regulation 21 CFR Part 11, on which Annex 11 of the EU-GMP is based, provides regulations on electronically stored documents which have electronic signatures. The use of the testo 184 data loggers in combination with the validatable ComSoft CFR software provides, among other things: Limitation of access to authorized persons, Audit Trails with time stamp, as well as electronic signatures, allowing a 21 CFR Part 11-compliant use of the data loggers.

## WHO/PQS/E06/TR05-VP.1

Due to the demanding requirements of the vaccine cold chain, the WHO and UNICEF's Supply Division have established equipment performance specifications and test procedures. The testo 184 logger family has been certified according to WHO/PQS/E06/TR05-VP.1 and complies with the international standards for temperature monitoring devices.

## The testo ComSoft Professional software

The ideal tool for fulfilling the regulatory requirements of GxP:

- Clear file structure for several measurement sites and data loggers
- Intuitive user interface guides you through the individual processes step-by-step
- Graphic readings profile for a clear display of the readings
- Uncomplicated configuration of start and stop criteria, measurement and storage intervals, and limit value settings
- Convenient export functions, e.g. for the further processing of data in Microsoft Excel or generating a PDF



**CFR ready**

# Overview of the testo 184 data loggers.



**testo 184 T1**



**testo 184 T2**



**testo 184 T3**



**testo 184 T4**



**testo 184 H1**



**testo 184 G1**

	<b>testo 184 T1</b>	<b>testo 184 T2</b>	<b>testo 184 T3</b>	<b>testo 184 T4</b>	<b>testo 184 H1</b>	<b>testo 184 G1</b>
Measurement parameters	Temperature	Temperature	Temperature	Temperature	Temperature/humidity	Temperature/humidity/shock
Exchangeable battery	-	-	✓	✓	✓	✓
Operating time	90 days	150 days	Unlimited	Unlimited	Unlimited	Unlimited
Battery life	-	-	500 days (at +25 °C and 15 min. meas. cycle)	100 days (at -80 °C and 15 min. meas. cycle)	500 days (at +25 °C and 15 min. meas. cycle)	120 days (at +25 °C and 15 min. meas. cycle)
Measuring range	-35 to +70 °C	-35 to +70 °C	-35 to +70 °C	-80 to +70 °C	-20 to +70 °C, 0 to 100 %RH	-20 to +70 °C, 0 to 100 %RH 0 to 10 g
Resolution	0.1 °C	0.1 °C	0.1 °C	0.1 °C	0.1 °C / 0.1 %RH	0.1 °C / 0.1 %RH
Accuracy	± 0.5 °C	± 0.5 °C	± 0.5 °C	± 0.8 °C (-80 to -35.1 °C) ± 0.5 °C (-35 to +70 °C)	± 0.5 °C (0 to +70 °C) ± 0.8 °C (-20 to 0 °C) ±1.8 %RH + 3% of m.v. at +25 °C 5 to 80 %RH ± 0.03 %RH / K (0 to +60 °C)	± 0.5 °C (0 to +70 °C) ± 0.8 °C (-20 to 0 °C) ±1.8 %RH + 3% of m.v. at +25 °C 5 to 80 %RH ± 0.03 %RH / K (0 to +60 °C) ±0.1 g + 5 % of m.v.
Storage temperature	-55 to +70 °C	-55 to +70 °C	-55 to +70 °C	-80 to +70 °C	-55 to +70 °C	-55 to +70 °C
Measuring cycle	1 min to 24 h	1 min to 24 h	1 min to 24 h	1 min to 24 h	1 min to 24 h	1 min to 24 h
Memory	16000 readings	40000 readings	40000 readings	40000 readings	64000 readings	64000 readings (temperature and humidity) + 1000 readings (shock)
Protection class	IP67	IP67	IP67	IP67	IP30	IP30
Alarm identification	by LEDs	by LEDs and display	by LEDs and display	by LEDs	by LEDs and display	by LEDs and display
Readout via NFC and mobile printer	✓	✓	✓	✓	✓	✓
Automatic PDF generation	✓	✓	✓	✓	✓	✓
Temperature acceptance test certificate according to DIN ISO 10204	✓	✓	✓	✓	-	-
Compatible with testo ComSoft CFR 21 Part 11	✓	✓	✓	✓	✓	✓




# Ordering information

## Data logger testo 184.

**testo 184 T1**

- Measurement parameter: Temperature
- Operating time: 90 days


Order no. 0572 1841




**testo 184 T2**

- Measurement parameter: Temperature
- Operating time: 150 days

Order no. 0572 1842




Wall bracket  
Order no. 0554 1841




**testo 184 T3**

- Measurement parameter: Temperature
- Operating time: unlimited

Order no. 0572 1843




Wall bracket  
Order no. 0554 1841




**testo 184 T4**

- Measurement parameter: Temperature
- Operating time: unlimited

Order no. 0572 1844




Wall bracket  
Order no. 0554 1841




**testo 184 H1**

- Measurement parameters: Temperature and humidity
- Operating time: unlimited

Order no. 0572 1845




Wall bracket  
Order no. 0554 1841



**testo 184 G1**


- Measurement parameters: Temperature, humidity and shock
- Operating time: unlimited
- Wall bracket included

Order no. 0572 1846



Accessories	Order no.
Wall bracket for testo 184	0554 1841
Mobile NFC printer for data logger testo 184	0572 0576
ComSoft Professional, professional software, incl. data archiving	0554 1704
ComSoft CFR 21 Part 11, software for requirements according to CFR 21 Part 11	0554 1705

testo 184 NFC App for free download



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