Be sure. testo

When transparency provides assurance.

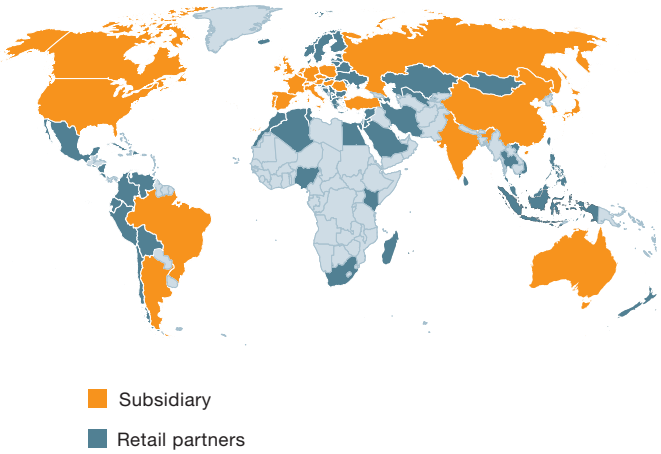
Data logger testo 184: Climate monitoring and data documentation when transporting pharmaceuticals.

High-tech from the Black Forest.

60 years of success in the field of measuring technology: a global company with roots in the Black Forest.

For 60 years, Testo has been known for creating innovative measuring solutions made in Germany. As a world market leader in portable measuring technology, we help more than 650,000 customers all over the world to save both time and resources, to protect the environment and human health, and to improve the quality of goods and services.

Our headquarters are in Lenzkirch in the Black Forest. However, for many years Testo has been a continually growing, global company, and it currently has around 2,600 employees. With our 32 subsidiaries and more than 80 sales partners, we are now represented on every continent.



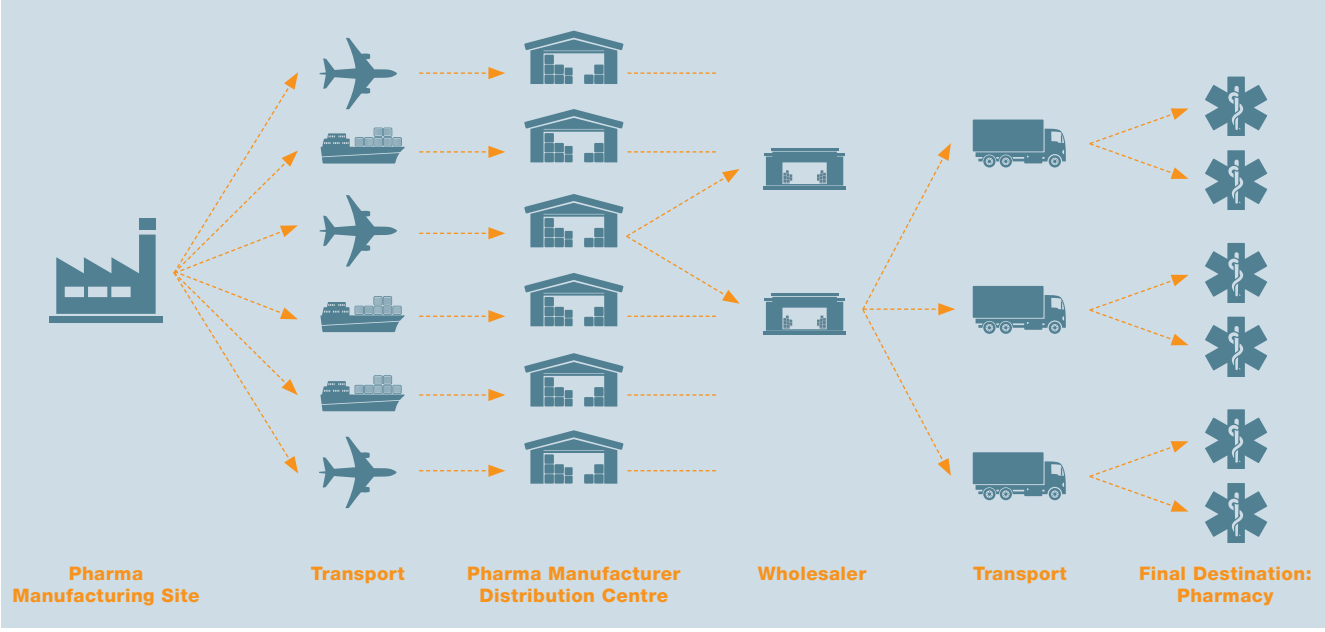
Transparency every step of the way.

More control when transporting sensitive pharmaceuticals.

When transporting pharmaceuticals, clearly defined temperature and humidity limit values need to be complied with in most cases – seamlessly and continuously. Breaching these limit values can result in irreversible damage to the active substances or to the composition of the pharmaceuticals.

The testo 184 data loggers enable you to monitor every step of the cold chain. The loggers keep things on track for you during the trip, monitoring the temperature when transporting sensitive pharmaceuticals – whether travelling by rail, air or road.

At the destination, you can see at a glance whether the configured limit values have been adhered to. To obtain more details, all you need to do is connect the logger to a PC – a report in PDF format is immediately created with all the relevant data.



The right measuring instrument for every requirement.

Overview of testo data loggers in the 184 series:
Monitor temperature, humidity and shock safely and reliably.

	testo 184 T1	testo 184 T2	testo 184 T3
Part no.	0572 1841	0572 1842	0572 1843
Measurement parameters	Temperature	Temperature	Temperature
Replaceable battery	–	–	✓
Operating time	90 days	150 days	Unlimited
Battery life	–	–	500 days (at +25 °C and 15 min. meas. cycle)
Measuring range	-35 to +70 °C	-35 to +70 °C	-35 to +70 °C
Resolution	0.1 °C	0.1 °C	0.1 °C
Accuracy	± 0.5 °C	± 0.5 °C	± 0.5 °C
Storage temperature	-55 to +70 °C	-55 to +70 °C	-55 to +70 °C
Measuring cycle	1 min – 24 h	1 min – 24 h	1 min – 24 h
Memory	16,000 readings	40,000 readings	40,000 readings
Protection class	IP67	IP67	IP67
Alarm indication	by LEDs	by LEDs and display	by LEDs and display
Readout via NFC and mobile printer	✓	✓	✓
Automatic PDF generation	✓	✓	✓
Temperature calibration certificate traceable according to ISO 17025	✓	✓	✓
Certified to EN 12830	✓	✓	✓
HACCP-compliant	✓	✓	✓
Compatible with testo ComSoft 21 CFR Part 11	✓	✓	✓

	testo 184 T4	testo 184 H1	testo 184 G1
	0572 1844	0572 1845	0572 1846
	Temperature	Temperature/humidity	Temperature/humidity/shock
	✓	✓	✓
	Unlimited	Unlimited	Unlimited
	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)
	-80 to +70 °C	-20 to +70 °C, 0 to 100% RH	-20 to +70 °C, 0 to 100% RH / 0 to 27 g
	0.1 °C	0.1 °C / 0.1% RH	0.1 °C / 0.1% RH / 0.1 g
	± 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.
	-80 to +70 °C	-55 to +70 °C	-55 to +70 °C
	1 min – 24 h	1 min – 24 h	1 min – 24 h
	40,000 readings	64,000 readings	64,000 readings (temperature and humidity) + 1,000 readings (shock)
	IP67	IP30	IP30
	by LEDs	by LEDs and display	by LEDs and display
	✓	✓	✓
	✓	✓	✓
	✓	–	–
	✓	–	–
	✓	✓	✓
	✓	✓	✓

The right software
is the perfect addition.

Simple, user-friendly and intuitive to use:
ComSoft Professional and 21 CFR Part 11.

ComSoft Professional

- The intuitive user interface guides the user through the individual sections step by step.
- Convenient export functions, e.g. for further processing the data in Microsoft Excel, and individual customization options for menus and functions.
- Different measuring locations and data loggers can be displayed in a clear tree structure, for example.

ComSoft 21 CFR Part 11

- Specially developed for the pharmaceutical industry.
- Validatable software, which meets all FDA (Food and Drug Administration) requirements.
- Conformity with the “21 CFR Part 11” guidelines has been confirmed by the independent Fraunhofer Institute.

Overview of the key functions.

Select the right software for your application:

	ComSoft Professional Part no. 0554 1704	**ComSoft 21 CFR Part 11** Part no. 0554 1705
Read out/configure logger	X	X
Storage cycle and measuring interval setting	X	X
Export data as .pdf or .csv	X	X
Display as diagram and table	X	X
Scientific and statistical evaluation (min./max.; mean value; limit value violation)	X	X
Create formulas	X	X
Report template	X	X
Data archiving	X	X
Electronic signature		X
Assignment of access rights on 3 user levels		X
Audit trail		X

There are clear rules
for transporting pharmaceuticals.

Overview of the most important standards for transporting pharmaceuticals: including WHO guidelines, GDP guidelines and also FDA Title 21 CFR Part 11.

EU EudraLex – 2013/C 343/01 “GDP Guideline”
In a GxP-regulated environment, particularly high demands are placed on quality management. GMP or GLP, but also particularly GDP (Good Distribution Practice) guidelines all play an increasingly important role. Distribution is an essential link in the value-added chain of medical and pharmaceutical products. Today’s distribution networks are becoming increasingly complex, and they incorporate an ever-growing number of different service providers. Compliance with these EU GDP Guidelines ensures control of the distribution chain and permanently improves the quality and integrity of medical and pharmaceutical products. Thanks to the testo 184 data loggers, GDP-compliant work won’t be a problem for you.

ISO 9001
ISO 9001 is probably the most significant international standard for quality management systems, and it guarantees framework conditions for products and processes that are in compliance with the regulations. In this regard, it is essential to be fully informed about the professional quality assurance of the suppliers involved in the process. Testo SE & Co. KGaA, which is an ISO 9001-certified company, fully complies with these requirements, and ensures that the standard is adhered to through internal audits as well as accredited external audits.

FDA Title 21 CFR Part 11
The FDA regulation 21 CFR Part 11, also called Part 11 for short, on which Annex 11 of the EU GMP is based, provides regulations on electronically stored documents which have electronic signatures. Using the testo 184 data loggers in combination with the validatable ComSoft 21 CFR Part 11 software provides access that is limited to authorized persons, audit trails with time stamps as well as electronic signatures, which means that you will be in compliance with 21 CFR Part 11 when you use data loggers from our testo 184 series in this way.

WHO Technical Report Series, No. 961, Annex 9
These guidelines set out the principal requirements for the safe storage and distribution of time- and temperature-sensitive pharmaceutical products (TTSPPs). They are based upon existing regulations and best practice guidance from a wide range of international sources, while accepting that local legislation and regulations will continue to take precedence. The target audience includes regulators, logisticians and pharmaceutical professionals in industry, government and the international agencies.

Be sure. testo

A good choice
for greater reassurance.

What testo 184 series data loggers have to offer:

Original size image

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

Simple operation
The testo 184 data loggers are intuitive to operate, and can be used without any special training or previous knowledge: the “Start” button begins data recording, the “Stop” button ends it.

Convenient readout
A report in PDF format with the transport data is automatically created as soon as the testo 184 is connected to the USB interface of a computer. This is suitable for long-term archiving according to PDF/A standard.

Simple configuration
A configuration file is stored on each testo 184 instrument, and this can be used to individually configure the data loggers very simply – no download, no installation, no user interface and no additional costs.

IT-safe
The testo 184 data loggers work without any software installation or download, so no IT problems are triggered by the firewall or the virus scanner.

Place-holder

www.testo.com/pharma-transport