Measurement data monitoring in the Black Forest
In the Parkapotheke pharmacy in Lenzkirch/Germany, the storage conditions and the quality of various medicaments are monitored and documented with the help of the automated humidity and temperature monitoring system testo Saveris. In order to ensure the effectivity of the pharmaceuticals, the temperature in the storerooms and sales outlet may not exceed a limit value of +20 °C (according to the Apothekenbetriebsordnung + 25 °C), and medicaments with a mandatory cold chain, such as antibodies, live vaccines, insulin or infusions, must be stored in a temperature range from +2 °C to +8 °C. Otherwise, the effective ingredients would be damaged and the patient exposed to increased risk. Alarms by SMS additionally allow a fast reaction to deviating values, and prevent considerable loss of inventory.

The Parkapotheke Lenzkirch
The Koch family has owned the Parkapotheke since 1962, and has been run by Jutta Koch since 1991. Shortly after having earned her licence, she recognized the urgent need for consultation services in chemists’ shops, and undertook further training in order to gain her qualification as an expert in retail pharmacy. From a typical country chemist’s shop, in the following years she shaped a successful modern business whose range of services is oriented towards today’s demands.
The challenge.
The Apothekebetriebsordnung (short: ApBetrO) and the new EU GDP guidelines make pharmacies, as the last link in the „integrated supply chain“, responsible for ensuring and proving the prescribed quality of the goods. According to § 4 of the ApBetrO, storage below a temperature of 25 °C Celcius must be possible. These storage requirements also apply in other rooms / areas (e.g. in the preparation and sales rooms), in which medicaments are stored.

In the EU GDP, pharmacies are described as part of the wholesale chain for medicaments. This leads to the consistent adherence to the same high quality requirements in logistics as in production. According to chapter 3.2, business rooms should be „designed and furnished in such a way that the required storage requirements are fulfilled.“ Continuing, in chapter 3.2.1, it states „Suitable equipment and procedures should be used for the monitoring of the ambient conditions in which the medicaments are stored. Ambient conditions which must be taken into consideration are, for example, temperature, light, humidity and the cleanliness of the business rooms.“

In order to be able to prove the correct storage conditions, a continuous documentation of the values is unavoidable.

The solution.
The measurement data monitoring system testo Saveris measures the temperature values in the storage of medicaments highly precisely, and documents them without interruption. The comprehensive alarm management as well as the automatic report creation allows the adaptation to different customer requirements. The transfer of the measurement data takes place via wireless and/or Ethernet probes to a base station. This monitors and documents all measurement data automatically. If limit values are exceeded, various alarm options, such as SMS/e-mail alarm or alarm relay are available. Remote alarms can even be given when the system is not connected to a running PC. Even in cases of power cuts, the recording of data continues without interruption with testo Saveris. All recorded data are centrally stored and archived in the validatable 21 CFR Part 11 software. This allows the comprehensive analysis and detailed evaluation of all recorded measurement data. testo Saveris thus provides a high level of security, reliable monitoring and considerable cost savings.

More information.
More information and answers to all your questions concerning measurement data monitoring with testo Saveris at www.testo.com.