Cold chain monitoring for pharmaceuticals

GDP compliant & ISO certified temperature and humidity tracking

Vaccines and pharmaceuticals are typically sensitive to exposure of temperature variations as well as shock, tilt, vibrations and light. They require a steady and controlled temperature environment throughout the entire supply chain. Temperature trackers that are placed together with the cargo during transportation can be used for monitoring an excursion event of a time temperature sensitive pharmaceutical product (TTSPP) cargo in various modes of transport including air shipments.

SHT43
ISO17025

Application challenges		Sensirion's solutions
1 GDP compliance as per WHO requires tracker with certified accuracy.	→	**1** Devices built on SHT43 platform inherit ISO17025 3-p temp calibration certificate.
2 Collecting devices every year for recalibration.	→	**2** Drift specified <0.01°C at a cert. accuracy of 0.48°C allows 2y operation according to WHO.
3 Battery application and live tracking desired	→	**3** Low power consumption with idle mode and flexible sampling rates.
4 Every country with different regulations	→	**4** By MRA* ISO (based on Swiss METAS) is equivalent to NIST traceability

SENSIRION

Sensirion sensor solution:

SHT43 humidity and temperature sensor
ISO 17025 certified

Size (LxWxH): 48 x 15.5 x 8.6 mm³

Additional sensor features

- ISO certified accuracy of ±0.48°C at 3-points @ -30°C, 0°C and 70°C

- Optional protective membrane for pollution reduction during operation

- Optional removable protective foil for protection during production

Other applications

- Tracker for time & temperature sensitive pharmaceutical products (TTSPP)

- Tracker for fresh & frozen food

- Temperature monitoring of cold chain storage facilities

- Temperature monitoring in trailers, containers and ULDs with active cooling

- Any NIST traceable applications

FAQs

- **What does ISO17025 certify?**
  ISO17025 certifies that each sensors accuracy has been tested individually by an ISO certified laboratory to be within a certain accuracy (± 0.48°C) at 3-points in temperature (-30°C, 0°C and 70°C).

- **How can I obtain the ISO certificate for a SHT43 sensor?**
  Through Sensirion's Libellus platform, a cloud service providing certificates and other sensor-specific data to customers of Sensirion and other interested parties. Currently, ISO17025 certificates are available for STS32, STS33, SHT33, and SHT43

- **Why does the ISO certification apply to the sensor rather than the system?**
  Since evaluation of measured data is handled on chip and the device only receives a digital value, the certified accuracy is independent of the device. But offsets coming from industrial design must be taken into account during product design.

- **Why is ISO equivalent to NIST?**
  NIST and many other accreditation bodies are part of ILAC mutual recognition agreement (MRA). This makes an ISO17025 certified sensors also NIST traceable.

- **What is the additional cost of the ISO17025 certification of an SHT43?**
  Each and every SHT43 is calibrated immediately after production. No additional cost besides the price of the sensor will be charged for download of the certificate on the Libellus platform.

Getting started

SHT4x evaluation kit

Useful documents

Datasheets, application notes, handling instructions, sample codes, step files, certificates

Related sensors

↗ SHT40 humidity/temperature sensor
↗ SHT41 humidity/temperature sensor
↗ SHT45 humidity/temperature sensor

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