Introducing TubeSense®

For secure distribution of temperature sensitive pharmaceuticals

Temperature controlled logistics specializes in the storage, preservation and transportation of cargo that is sensitive to atmospheric conditions and needs to remain within certain temperature limits. This is imperative for many pharmaceutical products, as spoiled drugs might have serious consequences on the health and wellbeing. Temperature controlled logistics failure leads to four risks: (1) A patient could be administered an unsafe product. (2) A lack of compliance with global regulatory and standards-based requirements can increase liability. (3) Thermal variability can lead to inconsistency of results between and within batches. (4) The shipment can be rejected unjustified by the Quality Department, leading to costly delays. Although temperature-controlled shipping is a state-of-the-art procedure, it usually does not cover the entire logistics chain. Temperature data is typically monitored by only a single device mounted on large packages or containers. The read-out is done in the warehouse room or pharmacy, but the subsequent trajectory from pharmacy to the patient as end-user is not monitored, while this is often the most critical step in the logistic chain.

TubeSense concept

TubeSense® is the perfect solution for tracking & tracing and monitoring transport conditions of protein pharmaceuticals and vaccines. Equipped with miniature NFC chip and temperature sensor of less than 1 cm², this re-usable logging device offers a smart solution for the logistics of temperature sensitive bio-logical medication, vaccines and biomedical samples (e.g. blood, urine) at individual item level.

TubeSense® mitigates risks by ensuring that shipping conditions remain within guidelines, exactly monitored and with all data securely logged in a database. Its compact form factor allows it to be easily and securely attached to any single vial, tube or container, making it particularly suitable for temperature logging of individual samples and packages. This makes TubeSense® a very cost-effective solution for all users in the complete logistics chain.

In addition to tracking & tracing and monitoring of transport conditions, TubeSense® also provides information to different stakeholders, including pharmacists, physicians, patients and governments. It holds information about the authenticity of the product and prevents manipulation (anti-tampering). It can further store detailed product information (company name, batch and lot number), and valuable information about administration of drugs or vaccines (location, date and time of administration, doctors code e.g. AGB code). Advice on usage and prescription information can be made available to the user just by tapping the vial/tube with a smartphone. Data are stored in a protected database that can be used for statistical analyses on variables in the effectiveness of vaccination programs, even many years after vaccination.

TubeSense® is prepared for dual frequency tag support (UHF RFID and NFC) and blockchain integration. This provides end-to-end visibility of shipments and products throughout the complete supply chain. If required, the TubeSense® logging devices can be equipped with additional light and shock sensors when needed for specific applications.

TubeSense® offers

- Item level identification of temperature sensitive pharmaceuticals and body fluid samples (e.g. blood, urine);
- Accurate temperature monitoring at given intervals, based on required temperature profiles (measurement intervals can be specified per batch);
- Non-volatile memory to store up to 15K readings at 0.3°C resolution;
- Its small dimensions, secure attachment (independent of tube size) and cost-effectiveness make it particularly suited for temperature logging of individual samples and packages;
- User-activation of temperature monitoring;
- Tracking and tracing during key phases in the process (shipment, moment of activation, e.g. at home, at laboratory entry);
- A secure, fast and easy Near Field Communication (NFC) based solution;
- A dashboard for analytics with statistics and key performance indicators (KPIs);
- A software as a service (SaaS) solution with a PC and mobile App front-end with customized 'look & feel';
- Optional integration with laboratory information management systems (LIMS);
- No personal data is used nor stored by TubeSense®, so no GDPR issues (after use all data are deleted after which the TubeSense® logging device can upon recepbe re-used);
- Anti-tampering functionality.

TubeSense® specifications

Temp. range	-40°C to +85°C	Data storage	Data is stored in a SQL database available for analysis (dashboard). API to LIMS available.
Temp. accuracy	±0.3°C in between 0°C and 40°C ±0.5°C in the range of -40°C and +85°C	Battery	CR1225 coin cell battery, 3V, 45-70 mAh*
Temp calibration	Not required (pre-calibrated, according to ISO/IEC 17025 temperature calibration procedure)	Battery life	~one year (depending on measurement frequency)
Logging interval	Adjustable from 10 seconds to 2.5 hour	Sensor location	Can be mounted on any vial or test tube, firmly attached by means of self-adhesive label
Start options	By removing the plastic tag or via NFC		
Stop options	When memory is full or user-programmable via NFC connection	Material	Resistant polypropylene enclosure
		Dimensions	40 x 15 x 4 mm (L x W x H)
Memory Size	~15.000 samples	Weight	<10 grams
Interface	NFC enabled smart phone or PC reader device	Warranty	1 year

A replaceable battery is preferred over all currently available rechargeable battery technologies because it is lighter and smaller, more cost-effective, super reliable and safe for shipping. And because of the closed loop use cycle, the batteries can safely be recycled after return to the lab.