

Introducing TubeSense®: a smart vial

to support the evolving Medtech markets and business models.

Secure transport of biomedical samples and temperature-sensitive pharmaceuticals



Safe healthcare logistics

When shipping biological samples or temperature sensitive pharmaceuticals, it is vital to ensure that shipping conditions remain within guidelines. From now on this can be monitored with TubeSense®. Equipped with NFC chip and temperature sensor, the newly designed re-usable TubeSense® temperature logging device offers a smart solution for the logistics of both biomedical samples (i.e. blood, urine) and temperature sensitive biological medication with simultaneous storage of sample specifications, sample data, transport time en temperature profile during transport and storage. All data can be saved and stored in a Laboratory Information Management System by one simple scan of the device.

Transport of samples for Home Collect Tests

Before sending a sample kit to a patient the TubeSense® temperature logger is attached to a vial and linked to the patient's lab file. After sample collection the patient initiates the temperature monitoring by removing a plastic tab that is attached to the logging device. During transport, the logging device registers the exact time and temperature of each sample. When the laboratory receives the sample tube with the connected TubeSense® logging device it is scanned using an NFC reader, upon which the temperature profile and transport time are read and sent together with proof of receipt data to the back-end system for data storage and further analysis.

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 un-



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. TubeSense® mitigates these risks by ensuring that shipping conditions are within guidelines, exactly monitored and all data logged in a database.

TubeSense® offers

- Item level identification of body fluid samples (e.g. blood, urine) and temperature sensitive pharmaceuticals;
- 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 be reused);
- Anti-tampering functionality.

How it works

Based on the parameters associated with a specific analysis, a temperature profile is entered in the TubeSense® SaaS (for example: 'temperature may not exceed 30 degrees during one hour and may not drop below freezing point, temperature measured every 15 minutes'). This data profile can be linked to the bar-codes prefix and suffix that are often used in most of the clinical laboratories.

Before sending a sample kit to a patient the TubeSense® logging device is attached to the test tube, and both the NFC identifier and the barcode are scanned and linked in this manner to the patient's laboratory file or clinical file. After receiving the vial at home, the patient collects the sample and initiates the temperature monitoring by removing a tab that is attached to the logging device.

Upon reception in the lab the vial with TubeSense® logging device is scanned using the front-end app and an NFC reading device (Windows PC or smartphone). The temperature results are read and sent together with proof of receipt data to the TubeSense® back-end system. Here, the temperature data is verified with the corresponding profile, after which the results are presented in the front-end app (for example: 'vial has been in good temperature conditions during the whole process') after which the sample can be accepted or rejected.

The TubeSense® back-end software stores temperature data, including track and trace data, the number of devices shipped, received, rejected or approved. Including date, time and information about the laboratory and the tests performed. From these data, a myriad of valuable statistics can be derived. All data are accessible via a web interface, including download options. Data can be exchanged with a LIMS using the available API.

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 | Material | Resistant polypropylene enclosure |
| Stop options | When memory is full or user-programmable via NFC connection | 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.